

An Educator's Perspective of Dr. Feingold's
K-P (Kaiser-Permanente) Elimination Diet
For Hyperkinetic Children and Others

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(Submitted in partial fulfillment of
the requirements for the degree of
Master of Education)

COLLEGE OF EDUCATION
B R O C K U N I V E R S I T Y
St. Catharines, Ontario

April, 1980

ACKNOWLEDGEMENTS

I wish to thank the following members on my Advisory Committee of the College of Education, Brock University, St. Catharines, Ontario: W. B. MacDonald, B.A., M.Ed., W. L. R. Crane, B.A., M.Ed., Ph.D., and J. P. Gram, B.A., M.Ed., Ph.D.

ABSTRACT

Do evaluation of the literature and a regional observational report support Dr. Feingold's claim that the K-P (Kaiser-Permanente) elimination diet improves the behaviours of hyperkinetic children, and others?

Dr. Feingold suggests that some hyperkinetic children, and other children as well, are genetically predisposed to intolerance of food additives, particularly food colours and flavours. He claims that the K-P diet, that eliminates salicylates and artificial food colours and flavours, improves the hyperkinetic child's behaviour, muscle co-ordination, and scholastic performance. Public acceptance of the K-P diet has outstripped acceptance in the medical and scientific communities. Evaluation of available data and additional studies are needed to arrive at a conclusion of acceptance or rejection of the K-P diet for hyperkinetic children and others.

My interest in the K-P elimination diet for hyperkinetic children is educational. My experience as an elementary school teacher in special education and in the classroom from K-8 has taught me that attentiveness is

crucial to learning. Hyperkinesis appears to impair a child's ability to attend. Learning problems appear, followed by behavioural and social problems.¹

If we accept the possibility of a relationship between diet and attentiveness, and attentiveness and school behaviours, then the diet-behaviour link could be of lay importance. For instance, if a diet such as the K-P diet could do what is claimed, substantial benefits could accrue to the child. One could, for example, improve a child's behaviours. One could identify attending disturbances early in the child's education, possibly minimizing, or eliminating future difficulties in school. Finally, the greatest benefit may be the fulfillment of the basic goal of our Ontario schools, that the child may develop happily and competently within our educational framework.²

This thesis reports evidence from the literature and from a regional observational investigation to determine the possibility of a link between the behaviours of children and Dr. Feingold's K-P elimination diet. The literature research examines (1) Dr. Feingold's concept of H-LD, (2) his K-P elimination diet, and (3) the response from three sectors, medicine, science, and the public. The regional investigation examines the observed behaviours of nine children in Regional Niagara during a nine-month

period on the K-P diet.

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I

DR. FEINGOLD'S CONCEPT OF H-LD
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LITERATURE DEALING WITH
CHILDHOOD HYPERKINESIS

Chapter 1

TERMINOLOGY

H-LD, hyperkinesis, hyperkinetic syndrome, hyperactivity are terms that are used interchangeably to refer to the same syndrome.¹ There are as many as thirty-eight labels for the syndrome;² the most commonly used are hyperkinesis and hyperactivity.³ According to Dr. Benjamin Feingold, the history of hyperkinesis dates back to 400 B.C.⁴ Recognition of the syndrome appeared in a children's verse of a century ago in Germany, "The Story of Fidgety Philipp".⁵ Until the 1960's, hyperkinesis was associated with brain injury.⁶ In 1966 Clements reported to the United States Department of Health, Education, and Welfare (DHEW) that not all children diagnosed as hyperkinetic were brain damaged⁷ and the syndrome became known as 'minimal brain dysfunction', or MBD.⁸ Currently, research is being directed toward finding a distinction between MBD and hyperkinesis,⁹ and toward subgrouping the hyperkinetic syndrome into distinct categories.¹⁰

Dr. Feingold's suggestion that H-LD, hyperkinesis-learning disability, is "one of the current scientific terms" is supported in the hyperkinetic syndrome literature.¹¹ Millichap and Fowler combined the two terms in the title of a drug therapy article, "Treatment of 'Minimal Brain

Dysfunction' Syndromes: Selection of Drugs for Children with Hyperactivity and Learning Disabilities".¹² Authier referred to the "Mixed Hyperkinetic and Learning Disability Type" as one of three types of MBD sub-grouped by Peters and others, in 1974.¹³

Silver suggested that when hyperkinesis and learning disabilities are present together, "the best purely descriptive label is 'the learning disability syndrome' or 'neurologically-based learning disabilities'".¹⁴ From the educational standpoint, Silver's first label is broad. By implication, it refers to learning disabled children in general, not to the specific group of learning disabled children who are hyperkinetic. The second label is specific but technical: perhaps it is more applicable to medicine than to education.

In a comprehensive questionnaire survey of forty-eight physicians, Sandoval and others reported that "the most frequently used diagnostic label is 'hyperactive-learning-behavior disorder, etiology unknown'",¹⁵ a label closely resembling Dr. Feingold's term, H-LD. By combining hyperkinesis and learning disabilities into the one term, H-LD, Dr. Feingold has effectively implied two objectives, (1) to specify a distinct group of children, and (2) to focus equally on the two components of the syndrome, hyperkinesis and learning disabilities.

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Chapter 2

DEFINITION

According to Loney and others, "most definitions of the hyperkinetic syndrome focus upon hyperactivity and/or inattention as necessary features".¹ Dr. Feingold accepts this focus and expands it to include learning difficulties. He defines the H component of H-LD as "excessive physical activity coupled with lack of concentration" and the LD component as "learning difficulties".² The term syndrome is defined as "a set of symptoms which occur together; the sum of signs of any morbid state, a symptom complex".³ The term hyperkinesis is derived from the Greek 'hyper' -- above, overly, more than normal, and 'kinesis' -- motion.⁴

The definition of hyperkinesis "is neither precise nor specific".⁵ However, Werry's definition is often cited:⁶

Hyperactivity has been defined as a chronic, sustained level of motor activity which, because of its excessive degree, is the source of continued complaint from both the child's home and his other environments.⁷

The problems with this definition are that the definition is subjective⁸ and its reliability cannot be measured. An objective definition has not yet been formulated; norms for activity levels do not yet exist.⁹

The hyperkinetic syndrome is defined behaviourally.¹⁰ Its definition is its symptoms, or characteristics. Lambert

and others summed up the problems in formulating a 'precise and specific' definition of the hyperkinetic syndrome:

It is defined by the absence of observable pathology and defined by behavioral characteristics that are reported subjectively; the task of definition is complex indeed.¹¹

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Chapter 3

DIAGNOSIS

Diagnosis of the hyperkinetic syndrome is made by a medical specialist.¹ There is no single test for diagnosis.² Tests that do exist are controversial³ and subjective;⁴ they help little.⁵ Connors suggested several tests that diagnose learning disabilities. However, he pointed out that these tests make no distinction between hyperkinetic children and children with other deficits.⁶ Actually, each child should be assessed on an individual basis,⁷ with the diagnosis based on a multi-dimensional evaluation⁸ that would provide the following information:

1. the child's medical history, which includes physical development, behaviours, and school progress;
2. the family history, its physical and behavioural aspects;
3. the child's major symptoms of the syndrome.⁹

Early diagnosis improves the prognosis.¹⁰ In a seven year follow-up study, Huessey and Cohen reported the following results.

Children identified in elementary school after second grade as being "hyperkinetic" were more likely than a control group to develop academic and disciplinary problems in early adolescence. ... Those pupils who were designated as being "hyperkinetic" only in second grade had a relatively good outcome as adolescents. On the other hand those pupils who were identified

three consecutive times as being "hyperkinetic" had a particularly grave prognosis.¹¹

Dr. Feingold suggests that the K-P diet he has developed may be used as a diagnostic tool for H-LD.¹² Its elimination design may test tolerance to additives; in the absence of the offending additive(s), the behavioural symptoms decrease or disappear.¹³ The intentional, or specific challenge strategy may test tolerance to additives as food items are slowly re-introduced into the diet.¹⁴ Unintentional infraction may test a child's tolerance to additives; the behavioural symptoms immediately re-appear on ingestion of the offending additive(s).¹⁵ However, Dr. Feingold has not explained the application of the K-P elimination diet as a measurable, diagnostic instrument. Researchers are presently investigating the efficacy of the K-P diet for hyperkinetic children.¹⁶

The K-P elimination diet is a comparatively new diagnostic procedure for childhood hyperkinesis. However, as an allergist,¹⁷ Dr. Feingold is continuing in an established dietary convention of diagnosis which dates back to Shannon in 1922. Shannon used an elimination diet design and "experimentation", now recognized as the specific challenge strategy, to identify offending agents in the food of eight children who exhibited "nervous manifestations" much like to-day's hyperkinetic symptoms.¹⁸ Juhlin and others used "provocation tests", the specific challenge strategy, to strengthen the validity of

diagnostic tests for allergic reaction in eight aspirin-sensitive adults to tartrazine, FD and C Yellow #5, a yellow food colouring additive.¹⁹ Chafee and Settupane used both the elimination diet design and infraction as diagnostic tools. Two separate infractions, promptly followed each time by a severe asthma attack, confirmed suspected aspirin sensitivity in an asthma patient.²⁰ By using the elimination design, Chafee and Settupane identified a cross-reaction of tartrazine and aspirin, and diagnosed the asthma patient to be tartrazine-sensitive, as well.²¹

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Chapter 4

SYMPTOMS OR CHARACTERISTICS

Since there is "a broad spectrum" of symptoms or characteristics, of the hyperkinetic syndrome, comparing the symptoms of H-LD with the literature involves three major aspects, (1) the number of symptoms, (2) the characteristics of H-LD, and (3) the new term for hyperkinesis, ADD.¹

NUMBER OF SYMPTOMS

The number of symptoms for childhood hyperkinesis ranges from seven to over one hundred (Table 4.1).²

Table 4.1 Number of Symptoms Cited in the Literature for the Hyperkinetic Syndrome

Source	Date	Number of Symptoms
Conners	1967	12
Conners	1969	39
Davids	1971	7
Feingold	Feb. 1977	45
Freedman Report	1971	8
Johnson, Prinz	1976	13
Laufer, Denhoff	1957	7
Sandoval and others	1976	131
Stewart and others	1966	31
Stewart	1970	27

Some symptoms are recognized as major symptoms and others as minor symptoms. Dr. Feingold listed forty-five symptoms. The Freedman Report recognized two core

symptoms and six others. There are two rating scales in Table 4.1, Conners' Teacher Rating Scale (CTRS, 1969) and Davids' Rating Scale for Hyperkinesis. Conners' rating scale is the most frequently used scale with teachers.³ Dr. Feingold used the CTRS in an early investigation.⁴ Two surveys are included in Table 4.1, Johnson and Prinz' teacher survey and Sandoval and others' physician survey. In Sandoval and others, the physicians ranked thirty-one symptoms important and fifty-one marginal, a total of eighty-two, supporting Dr. Feingold's statement that "almost a hundred different, but often similar, H-LD/MBD symptoms have been listed in medical publications over the years".⁵ The physicians ranked forty-nine symptoms not important.

H-LD CHARACTERISTICS

There are three aspects of Dr. Feingold's H-LD characteristics to consider, (1) the development of his symptomatology, (2) the three major symptoms, and (3) other H-LD symptoms.

Development

In his original classification of H-LD characteristics, which appeared in his book, Why Your Child is Hyperactive, Dr. Feingold listed ten major symptoms with associated characteristics below them.⁶ He revised his original classification of symptoms four times as he

developed his view of the characteristics of H-LD. His first revision, published in May 1975, still listed ten major items.⁷ Items 9, and 10, Ratio and Number per Family, were deleted and two new major headings, Cognitive Disturbances and Perceptive Disturbances, were added. Dr. Feingold presented his second revision to the United States Senate Subcommittee Joint Hearing on hyperactivity, on September 11, 1975.⁸ The ratio and number per family items were re-inserted as major headings, increasing the list of symptoms to twelve major items. The ratio figure was changed from boys 9:girls 1 to boys 7:girls 1. Dr. Feingold's third revision, published in November 1976, classified the twelve major items into three groups.⁹ His fourth and final revision of H-LD symptoms, published in February 1977, listed ten major items and classified them into three groups.¹⁰ Two items previously listed as major symptoms in Group I, Short Attention Span and Sleep Habits, were now listed under No Patience in Group I. Dr. Feingold's point that "this entire behavioral pattern is beyond the child's voluntary control" is well-supported in the literature.¹¹

The Three Major Symptoms of H-LD

Since hyperkinesis is defined behaviourally, H-LD is defined by its three core symptoms. The first two core symptoms, excessive physical activity and lack of concentration, are incorporated into the H component, hyperkinesis. The third core symptom, learning difficulties

is the LD component.¹²

Dr. Feingold classifies the two H, hyperkinesis, symptoms as Group I of the characteristics of H-LD.¹³ The two H symptoms are the same as two of the four symptoms of the hyperkinetic syndrome in the 1968 Diagnostical and Statistical Manual for Mental Disorders II (DSM II, 1968) of the American Psychiatric Association (APA), "over-activity" and "short attention span".¹⁴ These two major symptoms also concur with the Freedman Report's "core set of symptoms ... increase of purposeless physical activity [and] significantly impaired span of focused attention".¹⁵

Friend, and others, consider excessive physical activity to be "the essential feature of hyperkinesis".¹⁶ However, Bradley pinpointed the problem with this symptom as a criterion for hyperkinesis, in the first study of stimulant drug therapy for hyperkinetic children:

It is extremely difficult to measure motor activity per se apart from the individual's general behavior as shown by his mood and his intellectual ability. In our patients some decrease of motor activity was...noted.¹⁷

Dr. Feingold's most recent reference to the symptom, lack of concentration in hyperkinetic children, appears in The Feingold Cookbook for Hyperactive Children and Others with Problems Associated with Food Additives and Salicylates, which he and his wife co-authored.¹⁸ Connors, and others, consider lack of concentration to be "the key factor" in hyperkinesis.¹⁹ Of Bradley's five primary symptoms, "distractibility...

[which is] probably synonymous with 'short attention span', is the closest to Dr. Feingold's lack of concentration symptom.²⁰

Dr. Feingold classifies the third core symptom of H-LD, learning difficulties, into two groups of major symptoms, Group II, gross and fine motor incoordination and Group III, cognitive and perceptive disturbances.²¹ He cautions that "if the deficit is a critical one--e.g., an auditory perceptual or a visual perceptual disturbance--severe learning disabilities may result".²² The Freedman Report expressed concern that "a significant number [of hyperkinetic children]...have special learning or reading disabilities, in addition to the major symptoms".²³ Weiss and others accurately summarized the long-standing concern for the hyperkinetic child's learning deficit:

Their poor concentration, impulsive cognitive style, difficult behavior, and occasionally, specific learning disabilities all interact to produce academic failure.²⁴

The literature presents childhood hyperkinesis as a veritable "kaleidoscope of signs and symptoms" in number and in categories.²⁵

Other H-LD Symptoms

Opinions concerning Dr. Feingold's other H-LD characteristics range from agreement to minimal support. There is general agreement in the literature on four general characteristics of H-LD, the clinical pattern, a hyperkinesis-behaviour problems link, the situational-specific factor, and the chronological stages of H-LD. There is also general agreement on three specific characteristics, impulsivity, clumsiness, and IQ range. Opinion is divided on two points, compulsive-aggression, and male:female incidence ratio. There is minimal support for two characteristics, no patience and poor sleep habits.

General agreement--General characteristics. Dr. Feingold's description of the hyperkinetic clinical pattern seems to be right from the literature. Like Loney and others, he describes the pattern as "heterogeneous".²⁶ He refers to the clinical pattern's "variability and lability",²⁷ i.e., all children do not appear to have all of the symptoms, nor is each child's behavioural pattern predictable. For Dr. Feingold, unpredictability is a behavioural component.²⁸ For Loney and others, and Sandoval, it is an emotional one. They described the symptom as "emotional lability".²⁹ Silver's focus is behavioural, like Dr. Feingold's. Silver reported that the hyperkinetic child exhibits "multiple patterns of dysfunctional behavior".³⁰ It is generally agreed that the hyperkinetic symptoms range from "mild to

severe",³¹ and the focus in the literature is on identifying a general clinical pattern to facilitate standardization. Dr. Feingold appears to be the only one who focuses on behavioural changes in the individual child. He repeatedly states that,

Not only does each child have his own mosaic of deficits, but for any given child, the pattern may vary from day to day, and at times even from hour to hour.³²

There are innumerable references in the literature to the correlation of hyperkinesis and behaviour problems. The hyperkinetic child is described as "explosive", "a discipline problem", both at home and at school.³³⁻³⁴ The Freedman Report pointed out that some hyperkinetic children have "complex behavioral and personality problems".³⁵ Conners described the behaviour of the hyperkinetic child as "troublesome"; Knights and Hinton called it "problem behavior".³⁶

Dr. Feingold's concept of the relationship between hyperkinesis and behavioural problems has developed over the years and has become central to his hypothesis. As early as 1968, he included behavioural disturbances as a neurological symptom of allergic conditions induced by either synthetic or natural flavours.³⁷ In 1973, Dr. Feingold transferred his list of allergic conditions to childhood hyperkinesis and behavioural problems became a neurologic clinical pattern induced by artificial flavours and colours.³⁸ In May 1975, Dr. Feingold replaced the term

clinical patterns with the term adverse reactions and listed behavioural disturbances as the first of two neurological adverse reactions attributed to synthetic flavours and colours.³⁹ At the Joint Hearing on hyperactivity, Dr. Feingold testified that,

The adverse reactions [of food additives] affecting all systems of the body have been documented in the literature. They are pretty well known. Behavior is a new one.⁴⁰

He further stated that,

Of all the adverse reactions induced by the food colors and flavors perhaps the most dramatic and the most critical are the behavioral disturbances.⁴¹

Dr. Feingold suggests that the hyperkinetic child's behaviour may be situational specific, i.e.,

[There may be] a difference in the child's behavior at home and at school where the child must contend with a structured classroom environment, the need to learn, and the competition with peers.⁴²

Johnson and Prinz concluded in their teacher survey that hyperkinesis may be "situational".⁴³ Tarver and Hallahan reported that both Douglas (1972) and Bryan and Wheeler (1972) found evidence of excessive, purposeless activity, particularly among young children in a structured classroom situation.⁴⁴

Dr. Feingold divides the symptoms of the hyperkinetic syndrome into three overlapping chronological stages and specifies the symptoms that characterize each stage:

1. early infancy--the dominant features are restlessness, head banging, crib rocking, and sleeplessness;

2. nursery school to grade 2--impulsiveness, aggression, and short attention span become apparent;

3. grade 3 to adulthood--the above characteristics persist into and through puberty, into adolescence and, perhaps into adulthood.⁴⁵

Stewart and others noted that Chess had reliably demonstrated that "the predominant symptoms change from one stage of the child's life to another".⁴⁶ Kinsbourne, in a paper presented to the Canadian Paediatric Association in 1975, divided the hyperkinetic symptoms into three specific stages, infant to toddler, pre-schooler to school-age, and adolescence.⁴⁷

General agreement--Specific characteristics. Dr. Feingold's excitable-impulsive factor for hyperkinetic children is well-supported in the literature from Bradley (1957) to Sandoval (1977).⁴⁸ Lambert and others, and Johnson and Prinz, reported the unpredictability of the hyperkinetic child's behaviour.⁴⁹

Studies conducted by Tarver and Hallahan, Werry and others, Knights and Hinton, and Stewart and others, provide evidence for Loney and others' statement that clumsiness, which is a subheading in Dr. Feingold's Group II H-LD symptoms of gross muscle coordination impairment, is among "the most often cited symptoms".⁵⁰ The Freedman Report considered hyperkinetic children who have muscle coordination impairment to be fewer in number, but "more

severely afflicted".⁵¹

Concerning IQ, on September 11, 1975, Dr. Feingold informed the Joint Hearing on hyperactivity that hyperkinetic children usually have "a normal or high IQ".⁵² The following year, Lambert and others provided support for Dr. Feingold's statement when they reported in a review of drug studies that researchers found hyperkinetic children usually have "average to above average intelligence".⁵³

Divided opinions. There is divided opinion in the literature for two of Dr. Feingold's H-LD symptoms, compulsive aggression and ratio of boys to girls. Loney and others referred to the behaviour of hyperkinetic children as "antisocial".⁵⁴ The physicians in Sandoval and others' survey ranked "unusually aggressive in behaviour" as an important symptom.⁵⁵ On the other hand, DSM II included "aggressive behavior" under the heading Symptoms Associated [With Hyperactive Reaction] But Not Sufficient for Diagnosis, D (303.0).⁵⁶ Hyperkinesis and aggressive behaviour were two of the five separate factors that Connors developed from his teacher rating scale.⁵⁷ Loney and others' investigation into hyperkinesis and aggression as two separate dimensions concluded that hyperkinesis and aggression are independent of each other.⁵⁸

Dr. Feingold vacillates in his statistics on the ratio of boys to girls who are hyperkinetic. His one early figure of nine boys to one girl concurs with

Johnson and Prinz' estimate of 9:1.⁵⁹ His other early figure of 10 boys to 4 girls is close to Silver's estimate of 5:1.⁶⁰ Dr. Feingold quoted an imprecise range of figures to the Joint Hearing on hyperactivity, 5-6:1, 5-9:1, and 7:1.⁶¹ Dr. Feingold currently estimates the ratio of incidence of childhood hyperkinesis to be 7:1.⁶²

Minimal support. There is practically no mention in the literature of Dr. Feingold's no patience symptom for hyperkinesis. Stewart included it in his list of twenty-seven items.⁶³ Dr. Feingold's poor sleep habits sub-heading is mentioned as a hyperkinetic symptom only by physicians in Sandoval and others' survey. They considered sleep habits to be of marginal importance.⁶⁴

ADD

DSM III, the latest edition of the APA's manual for mental disorders, makes two changes in the section dealing with the hyperkinetic syndrome. The term for the hyperkinetic syndrome and minimal brain dysfunction (MBD) is changed to Attention Deficit Disorder (ADD).⁶⁵ The four characteristics listed in DSM II for the disorder, "overactivity, restlessness, distractibility, and short attention span",⁶⁶ are, according to Cantwell, summed up in a single symptom, "inability to attend" and are explicit in the DSM III term, ADD.⁶⁷ The APA's classification of the short attention span symptom of hyperkinesis as a specific disorder, ADD, may facilitate both "the

identification of homogeneous subgroups within the hyperkinetic/MBD syndrome" and the standardization of testing, diagnosis, etiology, and treatment of hyperkinetic children.⁶⁸

The literature generally supports Dr. Feingold's classification of symptoms of childhood hyperkinesis except for two, No Patience and Poor Sleep Habits. Dr. Feingold and educators concur that the focus is on the individual child. The new term, ADD, with its focus on attentiveness, may make an impact on the understanding of the hyperkinetic syndrome.

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Chapter 5

ETIOLOGY

There are many etiologies, or causative factors, for hyperkinesis.¹ Although "organic brain damage" is no longer considered to be an etiology,² the exact cause of hyperkinesis is not known.³ Theories of etiology divide into two general categories, the organic, neurological, or metabolic deficit theory, that focuses on the child's internal physical and psychological state, and the sociological theory that focuses on the child's place in his/her particular social system.⁴ Dr. Feingold subscribes to the organic deficit theory, according to Lambert and others.⁵ Like Wender, and Werry, Dr. Feingold discusses etiology in biological terms and focuses on birth-related factors.⁶ Since the organic theory lacks unequivocal evidence, it is not recognized as a valid etiology for hyperkinesis.⁷

There is divided opinion among those who hold the organic deficit view. Dr. Feingold concurs with Conners, and Stewart, in his belief that there is a genetic basis for hyperkinesis.⁸ He devoted an entire chapter in his book, Why Your Child is Hyperactive, to linking genetics, food additives, and hyperkinetic behaviours.⁹ He pinpoints artificial food colours and flavours as the most

frequently encountered "etiologiical agents"¹⁰ and he believes that there is a group of children who are "genetically predisposed" to these food additives.¹¹ Out of these two points, Dr. Feingold has formulated the following hypothesis:

Any compound in existence, either natural or synthetic, has the capacity to induce an adverse reaction in any individual with the appropriate genetic profile;

and he relates it to food additives and hyperkinetic children.¹² Marceca gave qualified support to Dr. Feingold's specific etiology theory with the statement that hyperkinesis "may be produced by various combined or singular causations".¹³

Dr. Feingold's etiology theory has developed from the allergy discipline, as did his characteristics of H-LD. His etiology theory began to formulate in 1968 with his article, "Recognition of Food Additives as a Cause of Symptoms of Allergy".¹⁴ He first reported his clinical observations linking behavioural disturbances to diet in his textbook, Introduction to Clinical Allergy, in 1973.¹⁵ By the time he wrote Why Your Child is Hyperactive in 1975, his theory had hardened into a three-point hypothesis.¹⁶ Dr. Feingold considers food additives to be "pollutants in the environment", causing hyperkinesis.¹⁷ He emphasizes that "these [hyperkinetic] children are normal: their environment is abnormal" (italics in original).¹⁸

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Chapter 6

PREVALENCE IN THE SCHOOL-AGE POPULATION

Dr. Feingold reports that there is a wide range of figures for the prevalence of hyperkinesis among school-age children. He quotes 500,000 as "a very questionable low-low", around 1 million as a low estimate, "varying to a high around 5 million".¹ Johnson and Prinz agreed with Dr. Feingold that prevalence of hyperkinesis is over 1 million,² but nowhere in the literature, except for Dr. Feingold, is prevalence quoted as high as 5 million. The statistical prevalence range in the literature is from a low of 3%³ to a high of 20%,⁴ generally agreeing with Dr. Feingold's low of 5%, but 8% below his high estimate of 28%. Dr. Feingold's high estimate of 40% for some California schools does not appear to be substantiated by other researchers.⁵

The Kolbye Report quoted the prevalence for hyperkinesis at 3% - 15%, adding that the most frequently cited estimates were 5% - 10% (Wender, 1971).⁶ It is interesting to note that the 1978 statistics of Lambert and others, and Loney and others, indicated that the estimated high had doubled from 10% to 20% since 1976 prevalence reports.⁷ This marked rise in prevalence within a two-year period may indicate that either more children are being diagnosed as hyperkinetic because of early identification and/or increased public awareness, or, that Dr. Feingold may be

right. Prevalence of childhood hyperkinesis may be rising in relation to the number of food additives that are in the food supply.⁸

To sum up, etiology theories for childhood hyperkinesis are as numerous as the terms and symptoms. Research into prevalence yields a wide range of statistics.

Looking ahead, prognosis research indicates two outcomes for childhood hyperkinesis, the one positive, and the other, negative.

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Chapter 7

PROGNOSIS

The prognosis for hyperkinetic children appears to be generally negative in the short term and into adolescence, psychologically, sociologically, and academically. The Freedman Report summed up the short term effects in the following statement:

The inability to control physical motion and attention may generate other consequences such as disturbed mood and behavior within the home, at play with peers, and in the schoolroom.¹

Psychologically, in the short term, Dr. Feingold finds hyperkinetic children to be unhappy and disorganized.² Sugarman and Stone, and Johnson and Prinz, referred to the child's poor self-concept.³ Sociologically, poor peer relationships are noted by Dr. Feingold, and others.⁴ Knights and Hinton pointed out that hyperkinetic children are teased by their peers.⁵ Dr. Feingold, and Johnson and Prinz, term the hyperkinetic child a social failure.⁶ Academically, Dr. Feingold points out two short term effects, (1) severe learning disabilities, as a result of an auditory perceptual or visual perceptual disturbance, considered by the Freedman Report to be secondary hyperkinetic symptoms rather than effects,⁷ and (2) task incompleteness.⁸ Others emphasize the repeated failure pattern.⁹

Dr. Feingold points out that the earlier the hyperkinetic child is treated, the better.¹⁰ According to Huessey and Cohen's follow-up study, and others, this point may directly affect the adolescent prognosis.¹¹ A hyperkinetic child who is not treated at an early age may develop emotional, psychological, and achievement problems. Several follow-up studies have been conducted to determine the prognosis in adolescence for hyperkinetic children.¹² In 1971 the Freedman Report observed that the outcomes are "ill-understood".¹³ In 1975 the Lipton Report reported that "there is little reliable information about the prognosis of hyperkinesis".¹⁴ By 1978 Weiss and others reported a firmer statement that "follow-up studies have shown that the prognosis of hyperactive children as they enter adolescence is relatively poor".¹⁵ Long term studies suggest that hyperkinetic adolescents appear to be more restless, impulsive, distractible and emotionally unstable than their peers.¹⁶

Dr. Feingold's prognosis for hyperkinetic children in adolescence is behavioural; it excludes the academic dimension. The hyperkinetic behavioural pattern has a psychological basis and develops into sociological manifestations. For Dr. Feingold, the prognosis is developmental. Like Weiss and others, Minde and others, and Stewart, Dr. Feingold predicts that the hyperkinetic child will have developed low self-esteem by adolescence.¹⁷ This poor self-image causes the adolescent to become unable to cope and may lead to withdrawal.¹⁸

The literature supports Dr. Feingold's theory that the prognosis is sociological on every point but one, abusiveness; it does not seem to be considered.¹⁹ It is generally agreed that the adolescent's antisocial behaviours²⁰ -- lying, stealing,²¹ and fighting²² -- lead to juvenile delinquency²³ and, in some adolescents, they lead to criminality.²⁴

Dr. Feingold only briefly alludes to outcomes for hyperkinetic children in adulthood. He suggests that the symptoms of impulsiveness, aggression, and short attention span that may appear at the nursery school to grade 2 level may, "at times", persist into adulthood.²⁵ DHEW, in a booklet for parents of hyperkinetic children, suggests a negative prognosis of adult delinquency, alcoholism, mental illness, and poor self-concept that projects Dr. Feingold's adolescent prognosis into adulthood.²⁶ On the other hand, in the same booklet, DHEW suggests a positive adult prognosis, that may be a function of the situational specific effect noted in hyperkinetic children:

The flexibility and independence often found in adult life may be more compatible for the hyperkinetic individual than the restricted world of childhood. [Sometimes] hyperkinetic behaviors, which cause problems during youth, become assets in later life. Follow-up research has shown that a number of adults who were hyperactive as children are lively, energetic extroverts who function very successfully in jobs that allow flexibility and individual freedom and which require endless energy, an outgoing manner, and spontaneity.²⁷

SUMMARY

On the one hand, the literature generally supports Dr. Feingold's H-LD philosophy in terms of the hyperkinetic syndrome, and on the other hand, Dr. Feingold has contributed to the literature. Dr. Feingold has added a new label, H-LD, to the terminology. He combines a behavioural component with an academic component, giving the syndrome two dimensions, a medical dimension -- H, hyperkinesis, and an educational dimension -- LD, learning disability.

There is no single test for diagnosing hyperkinesis. Dr. Feingold suggests that the K-P elimination diet may be used as a diagnostic tool, even though the efficacy of the K-P diet is still being researched. The hyperkinetic syndrome literature deals mainly with symptoms and it generally supports Dr. Feingold's characteristics. The APA's reclassification of the hyperkinetic syndrome, ADD, in DSM III, may have an impact on Dr. Feingold's concept of H-LD.

Dr. Feingold is a proponent of the genetic etiology theory and he focuses on food additives as a contributing factor in childhood hyperkinesis. His major premise is that

Any compound in existence, either natural or synthetic, has the capacity to induce an adverse reaction in any individual with the appropriate genetic profile.²⁸

Dr. Feingold seems to over-state prevalence and ratio data. However, recent figures in the literature suggest a prevalence increase. The literature supports Dr. Feingold's negative prognosis for hyperkinetic children,

both in the short term and in adolescence. However, adult prognosis may be either negative or positive, and is not dealt with by Dr. Feingold.

Dr. Feingold's perspective of the hyperkinetic syndrome is behavioural and he focuses on the individual child.

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II

DR. FEINGOLD'S RATIONALE FOR
THE K-P ELIMINATION DIET FOR
H-LD CHILDREN AND OTHERS

Chapter 8

EXPERIENCE AND EXPERTISE

Dr. Feingold's experience and expertise, his interest in food additives, and his focus specifically on artificial food colours and flavours form the basis of his arguments for K-P dietary management for hyperkinetic children and others.

EXPERIENCE

Dr. Feingold's professional experience is three-dimensional. He has acquired clinical experience, he has been involved in research, and he has written for various publications.

Clinical Experience

For a period of twenty-two years, from 1929 to 1951, Dr. Feingold was in private practice, first as a pediatrician, then as a child allergist, and finally in child and adult allergy. In 1951 he joined the Kaiser Medical Care Program in San Francisco, California, as chief of the

Department of Allergy where he has worked with adults and children.¹

Research

Dr. Feingold's research has been two-fold. He has conducted aspirin-sensitivity research² and he has been personally involved in programmes to study the relationship of food colours and flavours to childhood hyperkinesis since 1972.³ His interest in behavioural aspects of food colours and flavours developed between 1965 and 1968, during which period he diagnosed and treated over one hundred children for hypersensitivity to artificial food flavours and colours that manifested itself in behaviour problems.⁴ Since that time, Dr. Feingold's work with H-LD children has been, by his own admission, "purely empirical".⁵

The statistical data Dr. Feingold has reported for K-P elimination diet research programmes in which he has been involved seems limited, contradictory, and confusing. In June 1964 he reported to the AMA (American Medical Association) on 169 children in five separate programmes.⁶ One year later, in May 1975, he published a report in the American Journal of Nursing on 194 children in five separate programmes that gave response rate only.⁷ Programme I in the May 1975 report involved 100 children. On three other occasions, Dr. Feingold reported that his first programme involved 25 children.⁸ Dr. Feingold's references to six programmes in his book, Why Your Child is

Hyperactive, are mainly anecdotal and yield minimal statistical and research design data.⁹

Based on data Dr. Feingold reported on the number of subjects in each sample and the response rate, the six programmes he discussed in his book, Why Your Child is Hyperactive, may match up with the five programmes he reported, that same year, in the May 1975 American Journal of Nursing. Dr. Feingold's initial report on 25 subjects studied in 1972 may have been a segment of the 100 subjects studied in Programme I. The two Keithley studies, that totalled 33 subjects, may have been Programme II, that had 33 children in the sample. The Redwood Valley, California study, in May 1974, may have been Programme V: they both had 11 subjects and the same response figures. The Santa Cruz study, in the late spring of 1974, had the same size sample, 25, and the same results, as Programme III. The results of the Santa Clara study are the same as those of Programme IV. The incomplete data and apparent inconsistencies make valid assessment and comparison of Dr. Feingold's research programmes speculative, at best.

In addition to incomplete and confusing data, Dr. Feingold's criteria for response of children to the K-P diet has questionable validity. He reported that he used Conners' Teacher Rating Scale (CTRS, 1969) to confirm parent-reporting in the early investigations.¹⁰ However, he specified neither the programme(s) in which the scale

was used, nor the evaluation criteria. He reported neither the statistical data of the scale nor the correlation between teacher ratings and parents' observations.

Publications

In 1973, Dr. Feingold's textbook, Introduction to Clinical Allergy, was published. Between 1973 and 1977 Dr. Feingold authored twelve publications in professional periodicals concerning the ingestion of food additives, particularly food colours and flavours, and H-LD.¹¹

EXPERTISE

Dr. Feingold's expertise has the same three dimensions as his experience, clinical and research expertise, and expertise in publications.

Clinical Expertise

Dr. Feingold's clinical expertise enabled him to synthesize evidence into his basic hypothesis, which led him to focus on food additives and to zero-in on food colours and flavours.¹² The clinical evidence began in 1965, when the salicylate-free diet he prescribed for an adult allergy patient was responsible for the elimination of her hostile, aggressive behaviour, as well as the elimination of the allergy.¹³ By 1968 Dr. Feingold was focusing on children, having diagnosed over one hundred of them to be hypersensitive to artificial food colours and flavours. He published confirmation of the clinical

link between artificial food colours and flavours and behavioural disturbances in a June article of that same year and in his 1973 textbook, Introduction to Clinical Allergy. According to Buckley, Dr. Feingold was the first allergist to use the salicylate-free diet with children.¹⁴

Research

Through his research on aspirin-sensitivity, Dr. Feingold concluded that "the adverse reaction to artificial colors and flavors is nonallergic",¹⁵ and his focus on the effects of artificial food colours and flavours shifted from the allergy perspective to pharmacology.¹⁶

Publications

On June 26, 1973, Dr. Feingold formally introduced his suggestion of a link between hyperkinetic children and artificial colours and flavours in a paper he presented to the AMA.¹⁷ Dr. Feingold continues to focus on the adverse effects of artificial colours and flavours on hyperkinetic children and recommends the K-P elimination diet as a therapeutic programme.¹⁸

Dr. Feingold's medical practice, publications, and research in the field of allergy, led him over the years to focus on the effects of food additives, particularly food colours and flavours, on the behaviours of hyperkinetic children and others.

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Chapter 9

MACRO-FOCUS

Macro-focus is a focus on Dr. Feingold's rationale concerning food additives in general. There are two types of food additives, intentional and nonintentional. The nonintentional additives are "substances that accidentally become part of food"; the intentional additives are substances "purposely incorporated, in accordance with governmental regulations", during production, storage, and/or processing of food,¹ for "preserving, binding, coloring or flavoring".² In 1965 The National Science Foundation (NSF) classified intentional additives into thirteen categories with a total of 2764 items.³ Dr. Feingold points out that although the exact number of food additives is not known,⁴ the current estimate is approximately 4000 items.⁵

When considered with Dr. Feingold's concerns, the large number of food additives complicates the problem for individuals genetically predisposed to intolerance of certain compounds, whether natural or synthetic. Dr. Feingold's primary concern is behaviour: his secondary concerns are lack of knowledge and testing procedures of food chemicals in relation to behaviour. It is an accepted fact that certain chemicals, when ingested, do change behaviour. This has been the basis for drug therapy as a calming effect for hyperkinesis since 1937 and, conversely,

as a stimulating effect for other disorders.⁶ Through research, Dr. Feingold learned that haptens, low molecular weight chemical compounds,⁷ that are present in medication and in food additives,⁸ combine in the body with body proteins and produce antigens, which trigger adverse reactions.⁹ This mechanism has been suspected to be a genetic cause of behavioural disturbances in children. Haptens present in drugs during pregnancy are capable of crossing the placental barrier; they may have an adverse effect on the foetus that may later manifest itself in the child as behavioural disturbances.¹⁰ Dr. Feingold's concern is that, since haptens are also present in food additives, this same mechanism may occur during pregnancy from ingestion of food additives that may later appear in the child as hyperkinesis.¹¹

Dr. Feingold points out that food additives, particularly food colours and flavours, adversely affect all systems of the body¹² and he deplores the complete lack of knowledge in the following five areas:

the behaviour of chemical compounds in food additives in the body;¹³

"the precise identification of the specific factors among the thousands of food additives";¹⁴

the effects of food additives on behaviour;¹⁵

the mechanism by which food chemicals cause adverse reactions;¹⁶ and,

the dosage response to food additives.¹⁷

Dr. Feingold recommends multi-disciplinary research¹⁸ even

though it may require large samples of one thousand subjects or more,¹⁹ at considerable cost,²⁰ over many years²¹ to achieve the following three goals; to identify each compound,²² to learn the mechanisms and behavioural effects of the food additives, and, to institute preventive measures.²³

Dr. Feingold's other secondary concern is testing. Drugs are scrupulously tested pharmacologically, but food additives, which number in the thousands and contain the same chemical compounds as drugs, are not.²⁴ According to Dr. Feingold, testing of food colours has advanced little since 1907.²⁵ Twenty-six food flavours are listed in the 1973 Generally Regarded as Safe (GRAS) category and an additional 714 synthetic flavours appear on the Regulated list, compared with France's allowance of seven approved synthetics.²⁶

There are no tests to determine individual intolerance to food chemicals in relation to either dosage or cross-reactivity of food chemicals.²⁷ Dr. Feingold cites Swanson's research to suggest that food additive consumption, particularly food colour and flavour consumption, is dose-related.²⁸ As early as 1965, Randolph suggested a relationship between individual susceptibility to environmental factors and specific dosages of those factors.²⁹ Dr. Feingold has refined Randolph's suggestion as he focuses on artificial food colours and flavours as specific environmental factors, which, when ingested even in small amounts, may trigger adverse reactions in some children.³⁰

During his aspirin-sensitivity research, Dr. Feingold learned that tartrazine (FD & C #5) and aspirin cross-react to cause adverse effects, even though they are not structurally related.³¹ Dr. Feingold suggests that this same cross-reactivity may occur between food additives, particularly between food colours and flavours.³²

Dr. Feingold recommends that everything be tested, "each compound or class of compounds on the basis of benefit compared with risk".³³ Since adequate research within government agencies seems to be limited by existing policies, Dr. Feingold further recommends a modification in governmental regulations in the field of nutrition.³⁴

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Chapter 10

MICRO-FOCUS

Micro-focus is a focus on Dr. Feingold's rationale concerning artificial food colours and flavours. Although the food colours and flavours account for only three of the thirteen categories of food additives classified by the NSF in 1965,¹ Dr. Feingold points out that they account for 2146 of the 2764 items within the thirteen categories, or, for approximately 80% of the additives in the food supply.² The synthetic flavourings category ranks first, of the thirteen, and accounts for 1610 of the 2146 additives; the natural flavourings category ranks second with 502; and the food colours category ranks eighth with 34 of the 2146 additives.³ On that basis, Dr. Feingold considers food colours and flavours to be the most common causes of adverse reactions attributed to food additives.⁴ He further suggests that, of all the adverse effects of food colours and flavours, behavioural disturbances are the most critical and dramatic.⁵

Dr. Feingold is concerned with two aspects of food colours and flavours in the food supply, general trend and nutritional value. He sees a correlation between the apparent rise in the incidence of hyperkinesis and in food colours and flavours. He informed the Joint Hearing on

hyperactivity that,

A graph projected for the estimated incidence of H-LD over the past ten years parallels the Standard and Poor's curves for the dollar value for soft drinks and synthetic flavors over the same period.⁶

Food colours and flavours have no nutritional value. To use a term Dr. Feingold borrowed from Sweden, they are 'cosmetic' only.⁷ Food colouring is for eye appeal and food flavouring is for touch, scent, and taste appeal.⁸

As early as 1968, while still working in the field of allergy, Dr. Feingold addressed the issue of artificial colouring in medication, as well as in food. Following in the tradition of Lockey,⁹ and Chafee and Settipane,¹⁰ Dr. Feingold pointed out that,

Because food colors are used in the manufacture of medicinal tablets, capsules and syrups, drugs serve as a common vehicle for the ingestion of artificial colours. Because of this, drugs should be included in a consideration of food additives.¹¹

Dr. Feingold devoted a full chapter in his book, Why Your Child is Hyperactive, to the issue of coloured and flavoured medication for children.¹² In at least two other publications he criticized the use of dye coating on medication for children.¹³

To help the consumer, Dr. Feingold advocates not only full disclosure of colours and flavours on all food labels,¹⁴ as have allergists before him,¹⁵ but that a logo appear on all colour- and flavour-free food items, as well.¹⁶

Dr. Feingold is concerned over what he considers to be an unwarranted, general increase of additives, particularly artificial colours and flavours, in the food supply. He suggests multi-disciplinary research and changes in government regulations, to resolve the issues he has raised.

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Chapter 11

ROLE OF THE K-P ELIMINATION DIET

Dr. Feingold's rationale for the K-P elimination diet has five components, (1) for whom it is designed, (2) the nature of its design, (3) the carbohydrates factor, (4) the benefits of the diet, and (5) its success rate.

FOR WHOM IT IS DESIGNED

The K-P diet is designed for a particular subset of hyperkinetic children. It is designed for those children who are genetically predisposed to intolerance of food colours and flavours.¹ Dr. Feingold also recommends the K-P diet for children afflicted with the following disorders: seizures, retardation, autism, Gilles de la Tourette Syndrome, Down's Syndrome, enuresis, serous otitis, nystagmus, and strabismus.²

THE NATURE OF ITS DESIGN

The K-P diet is "a safe, benign modality".³ It adds nothing. It eliminates foods which contain a natural salicylate radical, colours, flavours, and the antioxidant preservatives -- BHT (butylated hydroxytoluene) and BHA (butylated hydroxyanisole).⁴ The benefits outweigh the risks. Dr. Feingold claims that there are no risks; there is no danger, no harm.⁵

CARBOHYDRATES

Because some children appear to manifest behavioural disturbances following ingestion of "simple carbohydrates", Dr. Feingold considers carbohydrates in the K-P elimination diet for H-LD, even though this consideration is not part of his hypothesis.⁶

THE BENEFITS

Dr. Feingold speaks of four benefits of the K-P diet for H-LD children.

1. Academically, the K-P diet child adjusts to the classroom environment⁷ and rapidly improves in academic achievement. Cognition, perception, mathematics, oral reading, and comprehension improve.⁸

2. Behavioural improvement is evident.⁹ Hostility, aggression, impulsiveness, and the tendency to perseverate are controlled. Peer relationships are improved. The child is calmer, setting into motion a chain reaction of improved concentration, longer attention span, and improved scholastic achievement.¹⁰

3. Physically, the K-P diet child achieves improved gross and fine motor control.¹¹ Academic, behavioural, and physical improvement appear to turn on and off in direct relation to infraction of the diet. A single infraction, in some cases, induces the full return of adverse effects.¹²

4. The K-P diet may seem restrictive. Actually, it is "liberal and nutritious".¹³

THE SUCCESS RATE

K-P diet success is measured within two perspectives: the individual view measured on a chronological basis; and, the general view measured in percent. Age is a determining factor. As has been noted, the younger the child, the more rapid and successful the improvement.¹⁴ The rate and degree of response appear to be relative to the age at which the child begins the K-P elimination diet (Table 11.1).¹⁵ For a child who has been taking medication for hyperkinesia there is a "wash-out period" for the drugs, which slows dietary management improvement.¹⁶

Table 11.1 K-P Elimination Diet Success Rate on a Chronological Basis

Age	Approximate Time Frame	Probable Response
Infant	24-48 hours	Complete
2-5 years	3-5 days	Complete
School age (young)	7-10 days	Complete
5-12 years	10-14 days	Complete
- on stimulant medication	3-6 weeks	Complete
- learning improvement	1-several months perhaps one year	Complete
Puberty		
- behavioural change	Spontaneous	Incomplete

Table 11.1 (continued)

Age	Approximate Time Frame	Probable Response
- psychological deficits	Persistent	Incomplete
- learning difficulties	Persistent	Incomplete
Postpubescent, adolescent	Several months	Incomplete

Two reasons are suggested for the slower and less complete success in older children; the psychological, self-explanatory reason, "learned behavior",¹⁷ and the neurological, more complex reason, "accumulative effect",¹⁸ or "residual deficit".¹⁹ Accumulative or residual effect is the amount of neurological impairment that has built up through the years, due to intolerance of food colours and flavours, that persists in spite of the elimination of the offending chemicals by the K-P diet.²⁰ The order of improvement on the diet supports the residual deficit theory: initial improvement is behavioural -- loss of hyperactivity, aggression, and impulsiveness; muscular coordination improves next; and cognition and perception improve last.²¹

The success rate of the K-P diet from 1965 to 1977 varied from 30% to 50%.²² The one exception to these figures is Dr. Feingold's report to the Joint Hearing on hyperactivity in 1975, of 30% to 70% success, with an

average of 50% success.²³ Dr. Feingold claims an increased success rate of 60% to 70% since more emphasis has been placed on the elimination of BHT and BHA from the K-P diet.²⁴

SUMMARY

In defence of K-P dietary management for H-LD children, Dr. Feingold constantly reiterates his rationale throughout his publications. He has developed this rationale from his professional experience and expertise. His evidence supporting the K-P elimination diet appears to be based mainly on anecdotal data that he has collected from clinical studies and reports from parents of H-LD children. Aside from descriptive charts, Dr. Feingold presents little statistical evidence or research design data to support his rationale.

Since food additives contain the same harmful chemicals as drugs, Dr. Feingold urges that food additives be subjected to equally rigorous research, testing, and government regulation. Dr. Feingold focuses on food colours and flavours as the major causes of behavioural disturbances in some hyperkinetic children.

Dr. Feingold credits the K-P diet with four specific benefits. The child benefits by improvement in three areas, academic, behavioural, and physical development, and, the K-P diet is nutritionally sound. The improvement rate of the K-P diet for hyperkinesis is age-determinant

and is currently estimated by Dr. Feingold to be from 60% to 70% successful.

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III

THE LITERATURE RESPONDS TO
DR. FEINGOLD'S RATIONALE
FOR H-LD

Chapter 12

EXPERIENCE AND EXPERTISE

EXPERIENCE

Clinical Experience

Buckley, in his defence of the K-P elimination diet to Dr. Sieben, pointed out that Dr. Feingold's rationale is not new in the field of allergy. Food dye sensitivity was first reported by the allergist, Stephen D. Lockey, in 1948.¹

Research

Dr. Feingold's rationale has been criticized for its empirical basis. His evidence was referred to by the Lipton Report as "empirical observations",² by Jukes, and others, as "anecdotal",³ and by Spring and Sandoval as "clinical experiences".⁴ The Kolbye and Lipton Reports, and others, found the early studies with which Dr. Feingold was involved to be "limited", "inconclusive", "inadequate", and "incomplete".⁵ Levine and Liden, and others, pointed out the need for more testing of the K-P elimination diet for more data.⁶

Spring and Sandoval, and others, argued that Dr. Feingold's "rather spectacular and specific claims are backed by only meager evidence" based on "meager research

of questionable vigor".⁷ They questioned the validity of the early studies in the following areas, research design,⁸ choice of population sample,⁹ improvement in behaviour, scholastic performance, perception and cognition,¹⁰ and, placebo response.¹¹

The Lipton Report questioned the reliability of Conners' Teacher Rating Scale for Dr. Feingold's purposes. They noted that the CRTS had not been "systematically employed to measure the parameters of the disorder [hyperkinesis] or improvement".¹²

Publications

In 1976, although several allergists had documented a food additives-behavioural problems link,¹³ the Kolbye Report stated that,

There is presently no evidence to indicate an association between an allergic or hypersensitive response to these agents [food additives] and hyperkinesis.¹⁴

As recently as March, 1977, Larkin reported that Dr. Feingold had not yet demonstrated the etiological connection of food additives to hyperkinesis.¹⁵

EXPERTISE

Clinical Expertise

Spring and Sandoval recommended a "moratorium on further public advocacy of the Feingold hypothesis" until efficacy of the K-P elimination diet is proven.¹⁶ Levine and Liden recommended further study of Dr. Feingold's hypothesis, possibly due to its unspecific focus.¹⁷

In November, 1976, Dr. Dunn, a general practitioner in Australia, reported replication of Dr. Feingold's initial success with an adult allergy patient. Dr. Dunn reported complete remission of hyperkinetic symptoms within three weeks.¹⁸

Research

O'Banion, Crook, Gale, Hawley and Buckley, allergists who are presently studying the adverse behavioural effects of food additives, support Dr. Feingold's hypothesis. However, they consider the adverse effects to be allergic rather than toxic.¹⁹

Publications

Dr. Feingold's June 26, 1973 paper to the AMA sparked the controversy over his K-P dietary management of hyperkinetic children. The medical community received it cautiously. However, "the public," as Bierman and Furukawa pointed out, "accepted the relationship between additives and behaviour as established fact".²⁰ Publications from varied medical disciplines support Dr. Feingold's hypothesis linking artificial food colours and flavours with hyperkinesis. Although Spring and Sandoval criticized Dr. Feingold's methodology, they acknowledged "the plausibility of a connection between hyperactivity and synthetic additives".²¹ Christopher Norwood, an environmentalist, suggested that food additives may be "a kind of missing link in the perception of environ-

mentally induced behavior problems".²² Ruth Heyman reported that NYICD (New York Institute for Child Development) includes an additive-free diet in their management of hyperkinetic children.²³ Dr. Dunn, the Australian GP, reported salicylate sensitivity in patients.²⁴ June Roth's book, Cooking for Your Hyperactive Child, included more than two hundred artificial-additive-free recipes and a four-day natural salicylate-free diet.²⁵ Gary Rogers' thesis, for his masters degree in clinical psychology, from North Texas State University, dealt with Dr. Feingold's rationale.²⁶ In 1978, consumer fliers were issued by two separate nutrition agencies. "Chemical Additives in Your Food", a chart issued by the Natural Health Bulletin in January, 1978, informs the public of the names of the additives, the function of the additives in food, the foods in which the additives are found, and the health risks.²⁷ Chemical Cookery, a pamphlet issued by CSPI (Center for Science in the Public Interest), introduces the public to the food additive issues and summarizes some safe and questionable additives.²⁸ "The Medical Letter", a "highly regarded publication circulated mainly among physicians", was not convinced by Dr. Feingold's rationale.²⁹ It stated:

Whether food coloring can aggravate hyperactive behavior remains to be determined.³⁰

The literature admits to a possible connection between food additives and hyperkinetic behaviours in children. However, it criticizes Dr. Feingold's rationale

on two points, the promotion of the K-P diet before proof of efficacy, and the absence of reliable, validated data.

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Chapter 13

MACRO-FOCUS

The function of intentional food additives, according to VandenHazel, is "to mask inferior quality and to add shelf life".¹ Kermode, in his comprehensive paper on food additives, reported that intentional food additives serve forty purposes.² According to Fremes and Sabry, some of those purposes are to preserve, texturize, colour and/or flavour the food product.³ Kermode under-quoted the number of classified intentional additives published by the NSF (2764) with his figure of 2500: CSPI's figure of 2800 different additives is close to the NSF figure.⁴ Dr. Feingold's figure of approximately 4000 grossly over-quotes all three, Kermode, NSF, and CSPI. Dr. Paul Yewchuk, who is currently conducting food research in Alberta, Canada, reports that there are approximately 3000 chemicals in the Canadian food supply.⁵

In their articles dealing specifically with Dr. Feingold's K-P diet, both Larkin and Norwood suggested the possibility of a genetic predisposition to overactive behaviour when stimulated by certain chemicals.⁶

Stimulant drugs were noted as early as the 1930's to have a calming effect on hyperkinetic children and were regarded by the 1950's and 1960's to be "panaceas".⁷

The Kolbye Report outlined a clear, brief explanation of the haptenic mechanism in the body.⁸

Huessy and Cohen, in a seven year follow-up study of five hundred hyperkinetic children, recommended primary prevention programmes of prenatal and paranatal care to minimize the incidence of hyperkinesis, giving credence to Dr. Feingold's "in utero" theory.⁹

The Kolbye Report recognized the dirth of knowledge concerning the behaviour of the chemical compounds that are in food additives, in the body. It described the adverse reactions attributed to food additives as poorly understood intolerance phenomena.¹⁰ The Lipton Report recognized the dirth of knowledge concerning the precise identification of the specific components of the thousands of food additives. It referred to the knowledge of the chemical composition of foodstuffs as "fragmentary".¹¹ Kermode admitted that it is difficult to determine the possible hazardous effects of food additives, particularly food flavours, on man.¹² The mechanism by which food chemicals, particularly food colours, cause adverse reactions was still unknown, even as recently as 1977.¹³

Dr. Feingold seems to be the only voice recommending coordination of the related disciplines and agencies for research into food additives and hyperkinesis. Kermode agreed with Dr. Feingold that research will take a long time¹⁴ and Gale agreed that it will be expensive.¹⁵ The World Health Organization (WHO), and others, recommended further research into the safety of food additives.¹⁶ Denenberg suggested that food additives are "inadequately

tested".¹⁷ Gale agreed with Dr. Feingold that food additives should be subject to the same rigorous testing as drugs.¹⁸ Testing for individual intolerance of food chemicals, advocated by Dr. Feingold, could take "decades", according to Norwood.¹⁹

In defence of Dr. Feingold's dose-related factor, Gale referred to Lockey's allergy and food additive research when he noted that "adverse reactions to minute amounts of food colourings have been recorded".²⁰

Cross-reactivity between food additives was still a mystery in 1978.²¹ In Erhoff's research (1976) on rats, cross-reactivity of two benign food additives resulted in marked toxicity and, cross-reactivity of three benign food additives killed all twelve rats within two weeks.²²

Admans and others added a new dimension to the cross-reactivity factor when their research suggested that tartrazine cross-reacts with DSS, a chemical used in laxatives, drugs, and foods, creating the potential for adverse reactions.²³

The United States government is taking action against food additives. The GRAS list is "undergoing scrutiny and revision".²⁴ FD & C Red #2, Red #4, and carbon black are banned; approval for ten cosmetic colours was withdrawn on October 26, 1976; fifty-two other colours need more testing; many food additives may require further testing.²⁵ Jukes noted that "requirements of safety for new food additives are far more stringent than formerly."²⁶

Codex Alimentarius Commission of the Food and Agriculture Organization and WHO are two international bodies that facilitate the exchange of toxicological data among governments and the evaluation of the safety of food additives.²⁷

Agreement with Dr. Feingold regarding food additives in general is the keynote of the literature. The United States government appears to be more actively concerned with the food supply than formerly.

Opinions regarding Dr. Feingold's rationale for food colours and flavours, specifically, are less clear-cut. Clinicians and some statisticians support Dr. Feingold's rationale: some researchers refute it with objective data.

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Chapter 14

MICRO-FOCUS

In his consumer report on the Feingold diet, Denenberg concluded that "we'd probably all be a lot better off without the artificial colors and flavors that now swamp our food supplies".¹ Kermode's 1972 estimate of 1100-1400 food flavours was considerably less than the NSF's 1965 total of 2112.² WHO recognized "a fairly short list of colors deemed to be safe" out of 140 evaluated.³

In 1976, Spring and Sandoval compared the 1949 and 1974 versions of the Coding subtest of the Wechsler Intelligence Scale for Children (WISC), to test whether the incidence of hyperkinesis was rising, as inferred by Dr. Feingold's Standard and Poor's correlation argument. They reasoned that lower mean scores in 1974 for this subtest would suggest increased incidence. They reported that "the 1974 means are considerably higher than the 1949 means for this subtest", and concluded that this finding suggested no increase in the incidence of childhood hyperkinesis over that period.⁴ On the other hand, Kermode observed that the increased use of food flavours over the past thirty years parallels the increase in the number of new types of food.⁵ Hawley and Buckley suggested that the "extensive use of food dyes and additives in 'quick energy' processed American food" is resulting in increased

incidence of hyperkinesis in the school population".⁶

VandenHazel subjectively commented that the function of food colours is "to deceive the consumer".⁷ Food colours have two functions, according to Kermode, (1) to give food an appetizing appearance, and (2) to enhance the appreciation of flavour.⁸ Jukes agreed with Dr. Feingold that food colours have no nutritive value.⁹

There is at least one response in the literature to Dr. Feingold's concern for coloured and flavoured medication for children. In 1978, the Natural Health Bulletin listed Yellow Dye #5 (Tartrazine) as an additive "used in prescription drugs, pain relievers and anti-histamines" that "can cause allergic reactions including wheezing, asthmatic symptoms and hives".¹⁰

Kermode recommended clear labelling to inform the consumer of the contents of food products.¹¹ Although FDA Commissioner Alexander Schmidt testified at the Inter-agency Collaborative Group on Hyperkinesis (Kolbye Report, 1976) that the FDA had no objection to a logo on colour-free and flavour-free foods, he pointed out that the FDA lacked the power either to enforce use of a logo or to recommend change in government regulations to ensure its use, until Dr. Feingold's hypothesis is validated.¹²

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Chapter 15

ROLE OF THE K-P ELIMINATION DIET

Researchers have suggested who may derive benefit from the K-P elimination diet. The K-P diet is brought into perspective with other therapies for hyperkinetic children. K-P diet success rate is compared with medication success rate.

FOR WHOM IT IS DESIGNED

Divoky, and others, agreed that the K-P elimination diet may help some children.¹ Roth recommended the K-P diet for autistic, learning disabled, emotionally disturbed, and MBD children.² Heyman suggested that the K-P diet may increase the learning ability of normal children.³ Norwood reported that a private pediatrician who treats hyperkinetic children with K-P dietary management also prescribes it for children "who are just cranky and unhappy for no real reason".⁴

THE NATURE OF ITS DESIGN

Dr. Michael Steinberg of the Philadelphia Board of Education Health Services and Dr. Colin-Williams, a pediatric allergist at the Hospital for Sick Children, Toronto, Ontario, two leading child-specialists, see no

harm in using the K-P elimination diet.⁵

CARBOHYDRATES

NYICD dietary management of hyperkinetic, learning disabled children, includes low carbohydrate consumption.⁶ The allergists Crook, Hawley, and Buckley have suggested that sugar may cause hyperkinesis.⁷

THE BENEFITS

The K-P Elimination Diet in Context with Other Treatments

Prior to comparing the literature's response to the four specific benefits accredited to the K-P elimination diet by Dr. Feingold, it may be helpful to focus on two aspects of the K-P elimination diet as a whole, to bring it into perspective as a treatment: (1) the benefits of the K-P diet relative to other therapies for hyperkinesis; (2) the rating of the K-P diet among Dr. Feingold's colleagues.

There are three generally accepted therapies for hyperkinetic children, diet, medication, and psychotherapy. Of the three, diet therapy is the least common.⁸ The NYICD designs individual diets based on protein, carbohydrate, and food additive content.⁹ Dietary studies are presently being conducted for glucose tolerance in hyperkinetic children.¹⁰

Although the efficacy of stimulant drugs for childhood hyperkinesis has not been unequivocally proven,¹¹ and many side effects may result from their use,¹²

stimulant medication is the traditional drug therapy.¹³ In a 1978 one-year study of over 5000 representative children, Lambert and others reported that "58% of the hyperkinetic school-age population were being treated with medication" and that "86% were treated with medication at one time or another".¹⁴ Research indicates that stimulant drugs do not improve academic performance.¹⁵ Kinsbourne, and others, pointed out that not all hyperkinetic children benefit from stimulant drug therapy.¹⁶ Kinsbourne further specified that,

Only two thirds of them do [benefit from drug therapy]: the remaining one third are actually adversely affected when given stimulants at levels sufficient to affect behavior.¹⁷

In fact, Dr. Feingold, and others, state that some hyperkinetic children do not benefit from any form of drug therapy.¹⁸ At best, medication helps in the short term; it is not a cure.¹⁹

Psychotherapy is a behavioural treatment²⁰ that may use the following programmes, either separately or in combination with each other, behaviour modification at home and at school,²¹⁻²² counselling,²³ and recreation programmes.²⁴

Sieben and Silver included Dr. Feingold's K-P elimination diet therapy with the following controversial therapies for children with learning disabilities: brain allergy (Wunderlich, 1973), hypoglycemia and trace elements (Cott, 1971, 1969), megavitamins (Pauling, 1968), patterning

(Doman and Delacato, 1968), sensory-integrative (Jean Ayres, 1972), allergic reactions (Philpott, Mandell, and von Hilsheimer, 1972), optometric training (Carlson and Greenspoon, 1968), and alpha-wave conditioning (Brown, Green, 1970).²⁵

The medical community is divided in its rating of the validity and reliability of Dr. Feingold's K-P elimination diet for hyperkinetic children.²⁶ Having reviewed current studies on the K-P diet, "The Medical Letter" concluded that "there is no convincing evidence that any diet is effective for the treatment of hyperactivity in children".²⁷ In a Nutrition Services bulletin, the Niagara Regional Health Unit informed the public that "there is no positive evidence that Dr. Feingold's additive-free diet provides the cure".²⁸ Cantwell, and others, labelled the K-P diet a fad;²⁹ Jukes called it a "shotgun prescription",³⁰ Friend a "placebo",³¹ and Divoky punned the additive-free diet, "food subtractives".³² Dr. Sieben called Dr. Feingold a "medical promoter".³³ Werry facetiously called him a "prophet".³⁴ Silver referred to Dr. Feingold as one of "the proposers of new treatments that promise... a simple or magical cure for the problem".³⁵

Admans and others, researchers of DSS, have accepted K-P dietary management.³⁶ It was accepted by Cott, the proponent of the controversial dietary treatment for hypoglycemia.³⁷ Dr. Powers, a private practitioner in the

United States, defended the K-P diet; Dr. Dunn, of Australia, recommended it.³⁸ The allergists, Dr. Feingold's closest colleagues, supported the K-P elimination diet for childhood hyperkinesis.³⁹

Dr. Feingold's Four Specific Benefits

In regard to the first of Dr. Feingold's four specific benefits of the K-P diet for hyperkinetic children and others, Friend suggested that stimulant drugs improve learning while the K-P elimination diet does not.⁴⁰ On the other hand, clinical evidence from two sources, NYICD and two Kaiser Permanente Centres, supported Dr. Feingold's claims of adjustment at school and improvement in scholastic achievement attributable to the additive-free diet.⁴¹

Phlegar and Phlegar assumed a diet-behaviour link in children and suggested five practical "implications" for educators, in their concern for the health and achievement of their students.

1. Schools could provide "nutrition minicourses" that would involve students, teachers, administrators, and parents in activities ranging from student-involvement in school cafeteria menu-planning to community involvement in nutrition workshops.

2. Educators could lobby for government legislation and school board adoption of policies that would restrict soft drink and junk food distribution in schools.

3. Educators could see that additive-free foods are provided in school cafeterias and vending machines.

4. "All students being considered for special education should have a physical examination from an orthomolecular physician or at best from a physician who is aware of the values expressed and the diagnostic procedures used by orthomolecular-trained physicians".

5. The 2% to 5% of the students who are chronic discipline problems and who have scholastic problems, or continuously fail school subjects, should be checked by an orthomolecular physician, or by a physician using the orthomolecular approach.⁴²

Opinions are divergent concerning Dr. Feingold's second specific benefit. The Lipton Report, and others, attributed behavioural improvement to "family dynamics" rather than to the diet, with the hyperkinetic child at the centre as the family works together to make a success of the K-P elimination diet.⁴³ Hawley and Buckley attributed behavioural improvement directly to the K-P diet.⁴⁴ Bolden and Shannon reported that the children are 'good', calmer, less frustrated, more attentive and that they experience improved peer and adult relationships.⁴⁵ Heyman observed improved peer relationships in hyperkinetic children treated at NYICD.⁴⁶ Wendy and Nestor Repetski, parents of hyperkinetic 4-year-old Alexander, attested to his "miraculous" behavioural improvement on the K-P diet.

His hyperactivity is greatly diminished; "he is happier, more cooperative, less irritable, less hostile, less belligerent."⁴⁷

Heyman's report of evidence of improvement in muscular coordination as a result of an additive-free diet at NYICD supported Dr. Feingold's third specific benefit.⁴⁸ Heyman, and others, attested to full return of hyperkinetic symptoms from infraction of the diet.⁴⁹

In response to Dr. Feingold's fourth benefit, the Lipton Report considered the exact nutrient content of the K-P elimination diet "difficult to assess".⁵⁰ Divoky and Werry warned that the K-P diet is not particularly nutritious; it is deficient in Vitamin C.⁵¹ By citing Dr. Feingold, Sugarman and Stone suggested that the K-P elimination diet is "restricted but nutritious" and "could replace some drugs as a way to treat hyperactivity".⁵²

THE SUCCESS RATE

Psychological problems follow learning problems. This was the reason given by Heyman for early identification of hyperkinesis.⁵³ Dr. Dunn's rapid and complete success with adult patients on the K-P diet contradicted Dr. Feingold's age-determinant factor at the same time as it replicated Dr. Feingold's first success.⁵⁴ Weiss and others noted in their five-year follow-up study of hyperkinetic children that the subjects exhibited the following "residual effects": impaired academic performance, poor social relationships, and inability to attend for a sustained period of time.⁵⁵ Spring and Sandoval rejected

Dr. Feingold's improvement sequence of first, behavioural improvement, followed by muscular coordination, and, finally academic improvement, on the grounds of the meagre data Dr. Feingold provided to support that sequence.⁵⁶

The Lipton Report compared K-P diet success rate with drug success rate. Both claim a 50% success rate with 2/3 of that being dramatic.⁵⁷

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Chapter 16

FAUS

Dr. Feingold has accomplished by accident what many consumer leaders vainly attempt to do by design.¹ Parental response to his rationale resulted in the organizing of the national Feingold Association of the United States (FAUS) in May, 1976, by Ruth Harbert, a Registered Nurse.² By the end of the first year, the association had grown to include fifty to sixty local chapters.³ There are currently 120 chapters, all non-profit volunteer organizations, with a total, in Divoky's estimate, of 10,000 families, and, in Morrison's estimate, 20,000 families.⁴ FAUS provides three services through its own publications and in the public media:

"it provides members with information about the effective use of the K-P diet";

"it provides a means for people to meet together regularly, to share their experiences and learn from each other";⁵

"it provides a way for interested professionals to learn how the diet works".

Its publications include the FAUS policy statement, FAUS annual convention materials, newsletters, menus, anecdotal reports, studies, reviews of studies, governmental and food

industry action reprints, and bulletins. The editor of the Delaware Medical Journal subjectively observed that parents receive Dr. Feingold with "god-like awe".⁶ Denenberg credited him with being "an effective consumer organizer".⁷

SUMMARY

The literature generally agrees with Dr. Feingold's rationale for the K-P elimination diet for childhood hyperkinesis. However, it rejects the evidence on which Dr. Feingold bases his rationale as lacking in focus and data. As Buckley suggested, opponents who are concerned that Dr. Feingold is promoting a 'fad' treatment may not be aware of developments in the field of child allergy that provide the foundation for Dr. Feingold's hypothesis. Opponents like Spring and Sandoval, and Sieben, are concerned that public acceptance has preceded proof of efficacy. They suggested that the K-P diet may be proven harmful to hyperkinetic children in the long term, and they included it with other controversial therapies. On the other hand, the K-P diet is being prescribed for hyperkinetic children, and others, by those who see no harm in it, as an alternative to drug therapy.

Paradoxically, medication is an accepted treatment for childhood hyperkinesis even though it is known to have hazardous short term effects and questionable long term effects.

Opinions of the benefits of the K-P elimination diet are divided. Opponents suggest that psychological factors contribute more to improvement than do dietary factors. Supporters have provided clinical evidence that dietary factors are the sole factors in improvement. Dr. Feingold's graph proving a rise in incidence of hyperkinesis was effectively upheld by some and was as effectively disproven by others. FAUS has contributed to the supportive literature through its own publications, e.g., newsletters, pamphlets, bulletins, and in the public media, e.g., in newspapers, periodicals, radio, and on television.

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IV

THE K-P ELIMINATION DIET
AS A THERAPY MODEL

Chapter 17

DEVELOPMENT OF THE MODEL

Buckley credited the beginnings of Dr. Feingold's K-P elimination diet to Stephen Lockey who designed an aspirin-free, salicylate-free diet in the 1940's and expanded it in the 1950's to exclude junk food and tartrazine (FD & C Yellow #5).¹ Dr. Feingold reported that the K-P diet evolved through five modifications to its present form, based on clinical investigations conducted concurrently by his fellow-allergists, including Stephen Lockey, and himself.² The K-P diet originally appeared in Dr. Feingold's editorial for Hospital Practice in 1973 as The Salicylate-Free Diet.³ Hawley and Buckley's 1974 version of Dr. Feingold's Salicylate Free Diet was essentially the same as their 1976 version of Lockey's Salicylate-Free Diet, indicating how closely Dr. Feingold and Stephen Lockey agreed, and perhaps collaborated, on a nutrition model for sensitivity to food colours and flavours.⁴ In all subsequent publications of the diet, Dr. Feingold has referred to the diet as the K-P elimination diet.⁵

In June, 1975, the Lipton Report noted a shift in Dr. Feingold's focus from a salicylate-free diet to a diet that included "other food ingredients", but it did not

explain the nature of these other ingredients.⁶ At that time, the diet excluded three types of food ingredients, natural salicylates, artificial food colours and flavours, and the preservative BHT, suggesting expansion of focus rather than a shift in focus.⁷ Over the next four years, Dr. Feingold's focus expanded still further. In 1976 he cautioned against carbohydrates for hyperkinetic children but he did not adapt the K-P diet to exclude them.⁸ In February, 1977, Dr. Feingold expanded the K-P diet to exclude the preservative BHA.⁹ In 1979 Dr. Feingold cautioned against additional chemical additives that may contribute to behavioural problems in hyperkinetic children and others: calcium propionate (a mold inhibitor), sodium benzoate (a preservative), synthetic chocolate flavouring, and milk.¹⁰ However, he has not expanded the K-P diet to exclude them.

Buckley, and Crook, suggested that the diet of hyperkinetic children should be entirely additive-free.¹¹ On the other hand, Harbert reiterated Dr. Feingold's statement that it is not necessary to eliminate all food additives.¹² In his work with Hawley, Buckley reported a moderate view. Hawley and Buckley recommended the elimination of food dyes and salicylates as dietary management.¹³ Sugarman and Stone gave an over-view of K-P elimination dietary management as they informed parents and teachers of hyperkinetic children that Dr. Feingold "feels that the salicylates found in food coloring and

aspirin should be avoided".¹⁴

Although Dr. Feingold's focus has expanded and, although the name of the diet has changed from salicylate-free diet to K-P elimination diet, the diet has remained basically the same since it was first published in Hospital Practice in 1973. The K-P diet currently distributed by FAUS is essentially the same diet that appeared in Dr. Feingold's book, Why Your Child is Hyperactive (1975).¹⁵ Two groups of foods are eliminated by the K-P diet:

Group I - natural salicylates;

Group II - artificial food colours and flavours.

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Chapter 18

K-P ELIMINATION DIETARY MANAGEMENT

K-P elimination dietary management is the same in the United States and Canada, and differs very little in Australia. The initial stage is to eliminate all foods in Group I of the diet, that is to say, all fruits and vegetables that contain natural salicylates, and, all foods in Group II, that is, foods containing food flavours and colours.¹ In the United States version, if the child responds favourably to the K-P diet, after four to six weeks, stage II begins. Group I foods may be re-introduced to the diet, one item at a time, at three to six day intervals, until every Group I item has been re-introduced, to test for favourable or adverse response.² In the Australian version of the K-P diet, the re-introductory process begins three to six months after the child has been on the diet.³ Adverse reaction to a Group I food item may indicate intolerance and the item is eliminated from the diet. The Australian version allows one week after adverse response to an item before re-introducing another Group I item.⁴

In stage II of K-P dietary management in The Feingold Cookbook, the foods containing natural salicylates are referred to as Group II in three instances. This

appears to be in error. Dr. Feingold classified foods containing natural salicylates as Group I in all previous references to the K-P diet and he permits the re-introduction of these foods into the diet if response is favourable.⁵ In the opening paragraph of Stage II in The Feingold Cookbook, Dr. Feingold explained that Group II foods are foods containing artificial colours and flavours, BHA, and BHT, and he insisted that these foods "must always be eliminated" (*italics in original*).⁶

Breakey, and others, discussed problems that may arise in implementing dietary management. Breakey noted that "it is not unusual for the child's behaviour to deteriorate dramatically during the first week of the [K-P] diet".⁷ Bolden and Shannon considered the first ten to fourteen days to be critical, as the family adjusts to the K-P diet and the hyperkinetic child's behaviour still appears to remain beyond the child's control.⁸ Harbert suggested that, if the K-P diet appears overwhelmingly restrictive or difficult to manage, a good starting point is the elimination of oleomargarine and cake mixes.⁹ However, Dr. Feingold prescribes strict compliance to elimination of all foods in Groups I and II for "the greatest assurance of a successful response."¹⁰ The ten current general instructions for managing the K-P diet with as few problems as possible, are basically the same as originally developed by Dr. Feingold in Why Your Child is Hyperactive.¹¹

According to the FAUS representative for the Niagara Region, Ontario, Canada, research into the ingredients of products, particularly those on the K-P diet, is conducted continuously, on a regional basis, by FAUS members in the United States and Canada. This helps K-P diet consumers to shop for additive-free food items in their local market-place, where products sometimes seem to change to 'new', 'improved', and/or 'fortified', with very little notice.¹²

SUMMARY

The K-P elimination diet lists two groups of food items to be eliminated from the diet of a hyperkinetic child, and others with behavioural disturbances. Foods containing the following are eliminated: natural salicylates, food flavours and colours, BHT and BHA. The United States and Canadian versions of the diet are identical; the Australian version differs only slightly. The two-stage dietary elimination design is similar to that which has been used by allergists for years.¹³ Both the K-P diet and the dietary management design have remained basically unchanged since Dr. Feingold first published the treatment in his book, Why Your Child is Hyperactive. FAUS members monitor foods in the market-place to help the K-P diet consumer.

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Chapter 19

K-P ELIMINATION DIET STUDIES

Studies to test the efficacy of the K-P elimination diet have been conducted in Australia, New Zealand, Canada, and in the United States. This chapter outlines the designs used for the K-P studies, summarizes and analyzes twenty-nine studies conducted to test the K-P diet, and reports three points made by critics of these studies.

STUDIES DESIGN

There are basically two types, or generations, of studies conducted to test the efficacy of the K-P elimination diet. The first generation studies were "dietary crossover" trials in which subjects were randomly assigned to a K-P elimination diet and control diet series for a period of

time, then were crossed over to the alternate series for an equal period of time.¹ Major first generation studies included Palmer and others (1975), Esther Wender (1975), Conners, Goyette and others (1976), Cook and Woodhill (1976), Harley and others Phase I (1976), and Salzman (1976).² Second generation studies are modelled on the "specific challenge design", in which children who have responded favourably to the K-P elimination diet are challenged with a crossover trial, as explained by Sobotka:

[They] are maintained on the K-P diet plus the addition of specific food items, half of which do not contain any artificial color or flavor and the other half of which do contain these additives.³

This design complies with experimental dietary design guidelines developed by the National Advisory Committee (Lipton Report, June, 1975) and the Interagency Collaborative Group on Hyperkinesis (Kolbye Report, 1976).⁴ Major second generation studies include Goyette, Conners and others (1977), Harley and others Phase II (1977), Williams, Cram and others (1978),⁵ J. H. Williams and others (1979),⁶ and Swanson and Kinsbourne (1978 and continuing).⁷

STUDIES TO TEST THE EFFICACY OF THE K-P ELIMINATION DIET FOR HYPERKINETIC CHILDREN

Twenty-five studies which have been conducted to test the efficacy of the K-P elimination diet for hyperkinetic children are summarized in Table format (Table 19.1). Six of the studies were conducted in Australia, two in Canada, one in New Zealand, and sixteen in the

United States. Four zoological studies, conducted in the United States to test the effects of food dyes on animal organisms, are also summarized (Table 19.2, pp. 139-39a).

Table 19.1 Studies to Test the Efficacy of the K-P Elimination Diet for Hyperkinetic Children

Study	Design	Time Frame
AUSTRALIA		
1. Breakey, Joan 1978	Clinical experiences in private practice -challenge -S= own control	Range: 2-16 months Avg: 6 months
2. Cook, Woodhill 1976	Clinical experiences -S=own control	1 year 7 months
3. Dumbrell, Woodhill, Mackie, Leelarthae-pin 1978	Double-blind cross-over trial with tartrazine challenge	1st 6 weeks of Levy and others' 16 week study

Table 19.1 (continued)

Subjects	Purpose	K-P Diet Components
1. 15+ children 8 adults 23+ 71 families	To test management of K-P diet	Australian version of the K-P diet
2. 1 f 4.5 years 1 m 10 months 13 m 5.75-13.0 years 15	To report clinical experiences which appear consistent with Dr. Fein- gold's theories	Australian version of the K-P diet
3. 14 m 4-8 years 2 f 16 of 22 Ss in Levy and others 1978	i) To report dietary data from Levy and others study ii) To evaluate nutritional adequacy of K-P diet	Australian version of the K-P diet

Table 19.1 (continued)

Results	Conclusions
1. 62 families - sufficient improvement to maintain diet 31 families -"dramatic" response - behaviour learning sleep habits	K-P diet extends diet therapy into behavioural areas; K-P diet = viable therapy to be combined with other therapies
2. Improvement-behaviours physical academic social	Findings appear to support those of Dr. Feingold
3. Vitamin B ₁ intake > Australian dietary allowances Vitamin C = adequate for all but one S	K-P diet = nutritionally sound = safe for use in treatment of hyperkinetic children - for children who are genetically predis- posed to certain chemi- cals in food

Table 19.1 (continued)

Study	Design	Time Frame
4. Fitzsimon, Holborow, Berry, Latham 1978	Double-blind cross-over trial - salicylate challenge	Range: 3-20 months
5. Levy, Dumbrell, Hobbes, Ryan, Wilton, Woodhill 1978	Double-blind cross-over trial with tartrazine challenge	16 weeks
6. Salzman, Louis K. 1976	Challenge -deliberate infraction	4 weeks

Table 19.1 (continued)

Subjects	Purpose	K-P Diet Components
4. 11 m 6-13 years 1 f 12	To assess whether a reaction to salicylates could be induced in Ss thought to be salicylate-sen- sitive, after maintaining K-P diet for longer than 3 months	Salicylate -acetylsalicylic acid
5. 19 m 4-8 years 3 f 22	To test the Feingold hypothesis	Australian version of the K-P diet
6. 15	To assess statistically behavioural changes in Ss on the K-P diet	Australian version of the K-P diet

Table 19.1 (continued)

Results	Conclusions
<p>4. Performance</p> <ul style="list-style-type: none"> -Knox cubes subtest of the Queensland Test = poorer Line-walking=more errors Finger-to-nose test = slower Sleep disturbances 	<p>General cognitive capacity may be impaired</p> <p>Motor co-ordination and speed may be effected</p>
<p>5. Rating</p> <ul style="list-style-type: none"> - mothers - improvement while on K-P diet - teachers, clinicians - no behavioural improvement as a result of diet <p>Tartrazine challenge produced no significant behavioural effect the following day</p> <p>Learning - no significant improvement</p>	<p>There may be time-limited "short-burst" effects on behaviour immediately following tartrazine challenge ingestion</p>
<p>6. 14/15 Ss - behavioural improvement within 4 weeks</p> <p>Infraction challenge</p> <ul style="list-style-type: none"> -7 Ss-pre-diet behaviour or worse 3 -return of enuresis 1 -rash 1 -sleep disturbance 	<p>This study demonstrates that the Australian version of the K-P diet significantly affects children with behaviour problems and learning difficulties</p>

Table 19.1 (continued)

Study	Design	Time Frame
CANADA		
7. Swanson, Kinsbourne 1979	Challenge -artificial food colour	Continuing
		Follow-up - 1 year
8. Williams, Cram, Tausig, Webster 1978	Double-blind cross-over 2x2 factorial design = 4 treatments	14 weeks
NEW ZEALAND		
9. Hindle, Priest 1978	Challenge Clinical, Anecdotal	At least 3 weeks

Table 19.1 (continued)

Subjects	Purpose	K-P Diet Components
7. Study 1: 8	To test artificial food colouring effects on cognitive performance	Artificial food colours
Study 2: 20		
Study 3: 9		
Follow-up: 50		
8. 26/29 27 m 2 f 6 - 14 29 years	To focus on the relative effects of a diet free of artificial food colours and flavours in com- parison to stim- ulant medication in managing hyper- activity in children	Modified Feingold diet - 9 artificial food colours
9. 8 m 2 f 4.11-11.9 10 years		
	To report trial of K-P diet therapy	New Zealand version of the K-P diet

Table 19.1 (continuing)

Results	Conclusions
<p>7.</p> <p>Study 2+ -after 1 hour-no change 2 -slight increase 3 -marked increase in performance problems</p> <p>Follow-up of Ss on K-P diet- -18 Ss (36%) still on diet -9/18=improved 9/18=marginally improved</p>	<p>Study 1: Colour can impair learning</p> <p>Study 2: Small amounts -no effect Larger amounts -significant effect</p> <p>Study 3: Red #3 ="OK" Other colours = "all bad"</p> <p>Follow-up -25 (50%) = favourable 25 (50%) = unfavourable</p> <p>Multimodal treatment</p>
<p>8. Diet effects were mixed Drugs + diet = best treatment effect Absence of both drugs and diet = highest levels of hyperactivity No statistical significance in infraction effect on behaviour</p>	<p>Stimulant medication = better results than diet Diet free of artificial colours results in a reduction of symptoms in some hyperkinetic children Infraction effects may last for a few hours</p>
<p>9. 5 Ss-well-established improvement 5 -initial improvement -not maintained</p>	<p>It has been possible to identify a group of children who have shown an unequivocal response to dietary management of their hyperkinesis</p>

Table 19.1 (continued)

Study	Design	Time Frame
UNITED STATES		
10. Brenner, Arnold	Control group 1 -15Ss	6 weeks or longer
	Control group 2 -12Ss	1 year follow-up
	Anecdotal	
11. Conners, Goyette, Southwick, Lees, Andrulonis 1976	Double-blind cross-over trial -control diet -K-P diet	12 weeks
12. Crook, William G. 1979	Clinical	5 years Follow-up
13. Goyette, Conners, Petti, Curtis 1977	Challenge -artificial colours Study 1 - Double-blind -challenge -placebo	8 weeks

Table 19.1 (continued)

Subjects	Purpose	K-P Diet Components
10. 32 6-14 years	An office study to check on the efficacy of the K-P diet with own patients - to disprove Feingold hypoth- esis	K-P diet
11. 15 6-12.11 years	To test additive-free food diet	K-P diet
12. 182 Follow-up 164	To investigate relationship between learn- ing problems, hyperactivity and diet	K-P diet
13. Study 1 - 16 4.7-11.8 years	To challenge K-P diet responsive hyperkinetic children with artificial colours	Artificial colours

Table 19.1 (continued)

Results	Conclusions
10. 11Ss-unequivocally excellent responses 8 -probably improved 13 -no change	Majority of aggravating agents = artificial colours and flavours K-P diet = feasible thera- peutic trial for all children having behaviour problems with poor impulse control and unusual irritability
11. Bulk of improvement on K-P diet = when K-P diet followed control diet Data = inconsistent	There may be a diet-order effect K-P diet may help some hyperkinetic children Vitamin C intake = lower on K-P diet Study = inconclusive
12. Colours, additives, flavours, etc. caused hyperactivity Difficult to separate reactions caused by sugar from those caused by colours and dyes	K-P diet has helped many hyperkinetic children Hyperactivity is most often caused by adverse re- actions to agents including food colours, dyes, additives
13. Study 1 -parent rating -57% mean reduction in behaviour problems on elimination diet -teacher rating -34% reduction 1-2 hours following challenge ingestion -performance deficit trend -data-no statistical significant difference	Study 1 -visual-motor coordination may be impaired by challenge

Table 19.1 (continued)

Study	Design	Time Frame
13. Goyette, Conners, Petti, Curtis 1977 (continued)	Study 2 - Single cross-over trial	
14. Grosek, Robert J. 1977	Clinical study	
15. Harley, Matthews, Ray Cleeland, Tomasi, Eichman, Chun, Traisman Phase I -preliminary report 1976 -complete analysis 1978 Summary Phases I and II 1977	I Double-blind cross-over trial II Double-blind cross-over -each Ss = own control	I Spring and summer 8 weeks Fall <u>10</u> 18 weeks II 13 weeks

Table 19.1 (continued)

Subjects	Purpose	K-P Diet Components
13. (continued)		
Study 2 -		
8 3.4-8.4 years		
5 3.7-10.2 years		
—		
13		
14. 1 m 4 years	To test the efficacy of the K-P diet	K-P Diet
15. I	I	K-P diet
36 m 6-12 years	To obtain objective laboratory data in addition to subjective parent-teacher ratings on hyperkinetic children under control and K-P diet conditions	
10 m 3-5 years		
46 m		
II	II	
9 of above 46 m	To determine if significant behavioural changes accompany ingestion of artificial food colours	

Table 19.1 (continued)

Results	Conclusions
13. (continued)	
Study 2 -45% mean reduction in behaviour problems on elimination diet -more problems during challenge period than during placebo period	Study 2 - short-burst effect from challenge Artificial food dyes may impair and disrupt behaviour of children, particularly of younger children
14. Significant reduction in hyperactivity in 2 of 4 measures -maintained by S after K-P diet terminated	Additive-free diet was not instrumental in reducing hyperactive behaviour
15. I	I
Classroom - no signif- Laboratory - ican change Diet order-no significant effect Neuropsychological- no supportive evidence for K-P diet Parent-teacher ratings -consistent for 4Ss =improved behaviours Hyperactivity-no significant decrease	Overall = negative, non-supportive Younger children may respond to K-P diet better than older children
II	II
1Ss = worse Data analysis - no difference	Little support for Dr. Feingold's hypothesis

Table 19.1 (continued)

Study	Design	Time Frame
16. Harper, Goyette, Conners 1978	Open clinical trial S = own control	I 5 weeks -2 weeks baseline 3 K-P diet
		II 8 weeks
17. Mattes, Gittelman- Klein 1978	Double-blind multiple cross-over -S = own control	12 weeks
18. Noonan, Roberta L. 1977	Clinical trial	14 days

Table 19.1 (continued)

Subjects	Purpose	K-P Diet Components
16. I 47 m 7 f 54	To assess nutritional adequacy of a diet eliminating FD & C certified colours and artificial flavours and to determine whether the changes in the diet produced nutritional variation from a normal diet	Foods containing FD & C certified colours and artificial flavours
II 13		
17. 1 m 10 years	To demonstrate K-P diet effect in S who had previously evidenced behavioural improvement on the K-P diet	Artificial food colourings
18. 1 f 14 years	To study effects of food and food additives on hyperkinesis	K-P diet

Table 19.1 (continued)

Results	Conclusions
16. I No significant nutrient intake difference	Nutritient intakes generally meet RDA -Recommended Dietary Allowances Behavioural improvement in 50% of Ss
II Same as the above	
17. Worsening behaviour = irritability, not hyperactivity	Results fail to support contention that artificial colourings are instrument- al in inducing significant change in hyperkinetic symptomatology Only a percentage of hyper- kinetic children are helped by the K-P diet
18. Day 3-dramatic improvement in attitude, social behaviour Comprehension Sitting still - improved Concentration Impulsiveness - no change	Study supports theory that sugar, artificial flavours, and colours, nitrates, salicylates, and MSG (monosodium glutamate) can effect a child's behaviour and learning

Table 19.1 (continued)

Study	Design	Time Frame
19. O'Banion, Armstrong, Cummings, Stange 1978	Clinical case study -S = own control	32 days
20. Palmer, Rapaport, Quinn 1975	Controlled trial	7 days
21. Rapp, Doris J.	Sublingual challenge testing	Study 1 = 7 days Study 2 - 12 weeks

Table 19.1 (continued)

Subjects			Purpose	K-P Diet Components
19.	1 m	8 years	To test behavioural effects of certain foods	Food additives
20.	79 m	6-12 years	To compare consumption of food additives in a group of school-age hyperactive children and their unaffected peers	K-P diet
21.	Study 1 - 18 m 6 f 24	5-16 years	Study 1 - To determine if dyes, foods, or allergy relate to increased activity in some children	4 food colours
	Study 2 - 17 of above	24	Study 2 - To determine if sublingual food or food colouring may be of diagnostic value	

Table 19.1 (continued)

Results	Conclusions
19. Reaction to wheat, corn, tomatoes, sugar, mushrooms, dairy products -shown by behavioural disorders	Some foods appear to be related to different disruptive behaviours than others Length of reaction time varies from $\frac{1}{2}$ hour to several days
20. No significant difference in consumption of food additives between the 2 patient groups	Findings are in contrast to Dr. Feingold's proposals that hyperactive children consume larger than normal amounts of food additives K-P diet may help a sub-group
21. Study 1 - 12/23-moderate to marked improvement 2/15-discontinued all drugs Study 2 - 11/17 of above -moderate to marked improvement 7/11-discontinued all drugs 6/15-discontinued all drugs within 6 weeks 6/17-slight or no improvement 1/6-discontinued drugs	Study 1 - Parents-ingestion of food colouring and other offending agents continued to be followed by hyperactivity Study 2 - Sublingual dye testing appeared to be effective in distinguishing most children who were later found to react repeatedly to food colouring

Table 19.1 (continued)

Study	Design	Time Frame
21. Rapp, Doris J. 1978 (continued)		Follow-up - After 18 months
22. Salamy, Joe 1979	Double-blind randomized cross-over trial -placebo challenge	2 weeks
23. Stine, John J. 1976	Anecdotal Clinical report	5 months-1S 2 months-1S

Table 19.1 (continued)

Subjects	Purpose	K-P Diet Components
21. (continued) Follow-up - 14 of above 17	Follow-up - To evaluate the benefit of a diet that omitted major suspect food and food colouring	
22. 4	To test effects of food additives on hyperkinetic children	K-P diet
23. 1 m 5.11 years 1 m 4.4 years 2	To report clinical improvement of Ss on K-P diet	K-P diet

Table 19.1 (continued)

Results	Conclusions
<p>21. (continued) Follow-up - 5/14-slight or no change after 1 week -4/5=same 1/5=moderate improvement 9/14-moderate to marked improvement after 1 week -7/9=significant improvement 2/9=only slight improvement 7/24 reacted to both sublingual food colouring and foods 10/21 reacted to both food colouring and at least one food during oral challenge ingestion</p>	<p>Follow-up - The prolonged beneficial effects (12 weeks) cannot be attributed to the psychological benefits of short-term dieting</p>
<p>22. Hyperkinetic children exhibited a greater degree of physiological responsiveness to both placebo and additives than did controls</p>	<p>Findings support contention that some hyperactive children may be adversely affected by food additives</p>
<p>23. S1-1 month-moderate decrease in hyperactivity and distractibility 5 months-report of teacher, parents, physician -above improvement =sustained S2-improvement --parents-immediate --teachers-6 weeks in distractibility, temper, motor activity; -10 weeks -marked improvement in attention span, adaptability, social skills</p>	<p>Improvement = gradual, not immediate K-P diet = safe; no side effects -may be considered as a therapy for hyperkinesis</p>

Table 19.1 (continued)

Study	Design	Time Frame
24. Wender, Esther	Challenge trial -each S=own control	7 weeks
		Follow-up - After 3 months
25. Williams, J. H. and others 1979	Double-blind challenge and placebo trial	77 days

Table 19.1 (continued)

Subjects	Purpose	K-P Diet Components
24. 11 3-9 years	To test the efficacy of the K-P diet	K-P diet
Follow-up - 3 of above 11		
25. 22 1-7 years	To test whether ingestion of artificial food colours can influence behav- iour in allegedly susceptible children	Individualized, modified K-P diet; 7 food colours

Table 19.1 (continued)

Results	Conclusions
<p>24. 4 weeks- 7-initial improvement 4-no improvement 7 weeks- 6 of above 7-returned to baseline behaviour</p> <p>Follow-up - All 3 Ss who chose to maintain diet had discontinued it</p>	<p>Almost impossible to interpret results with any kind of firmness Initial improvement may be due to Hawthorne effect</p> <p>Follow-up - No continuing beneficial effects</p>
<p>25. 21/22 failed to support hypothesis 1/22 f, age 3, one of the youngest and lightest - adverse effect 22/22 showed no evidences of delayed response</p>	<p>S who responded adversely to challenge indicates the possibility that reaction may be dose-related A behavioural effect can be demonstrated with food colourings in amounts less than the ADA in susceptible children K-P diet = nutritionally adequate</p>

^aFor sources, see nn 19.8-19.32.

STUDIES ANALYSIS

Four of the twenty-five studies summarized in Table 19.1 do not support Dr. Feingold's rationale regarding the K-P elimination diet for hyperkinetic children, Mattes and Gittelman-Klein (1978), Grosek (1977), Harley and others Phases I and II (1977), and Palmer and others (1975). In a review of K-P diet studies, Williams and Cram pointed out that Palmer and others did not test Dr. Feingold's suggestion that even minute amounts of the offending agents may cause adverse reactions in hyperkinetic children who are genetically predisposed to those agents.³³ Palmer and others tested the amount of additives consumed by a group of hyperkinetic children as compared to the amount consumed by a control group, and in so doing, they focused on quantity ingested. Dr. Feingold focuses on resulting individual behaviours following ingestion. Two studies, Conners, Goyette and others (1976) and Esther Wender (1975), were inconclusive because of inconsistent data.

Some studies suggested support of Dr. Feingold's rationale regarding the role of food colours and flavours. Crook (1979) and Brenner (1977) agreed with Dr. Feingold that, of all the offending agents, food colours and flavours are the most frequent causes of adverse reactions.³⁴ Evidence from four studies indicated that food colours and flavours impair motor and cognitive performance in hyperkinetic children, Swanson and Kinsbourne (1979), Fitzsimon

and others (1978), Goyette, Conners and others (1977), and Salzman (1976).³⁵ Levy and others (1978) and Goyette, Conners and others (1977) noted a short-burst effect. I.e., adverse reactions that may occur immediately following ingestion of food colours and flavours appear to be of short duration. Swanson and Kinsbourne (1979) and J. H. Williams (1979) agreed with Dr. Feingold that artificial colours and flavours may cause adverse reactions. However, their findings indicated that the reactions may be dose-related, contradicting Dr. Feingold's suggestion that minute amounts of an offending agent may trigger an adverse reaction. Kinsbourne reported that small doses of an offending agent had no effect; larger doses had a significant effect. J. H. Williams considered the dosage to have been too small to affect 21 of the 22 subjects in the FDA study. The one subject who did respond to the challenge dosage was one of the lightest and youngest children in the sample.

Some studies suggested support of Dr. Feingold's rationale regarding the role of the K-P diet in relation to artificial food colours and flavours. Dumbrell and others endorsed the K-P elimination diet for "those children who show a genetically determined sensitivity to certain chemicals in foods".³⁶ This endorsement supports Dr. Feingold's basic premise for the K-P diet for hyperkinetic children and others, that,

Any compound in existence, either natural or synthetic, has the capacity to induce an adverse reaction in any individual with the appropriate genetic profile.³⁷

Six studies gave qualified support to Dr. Feingold's suggestion that there may be a sub-group of hyperkinetic children who respond favourably to the K-P diet, Harley and others Phase I (1978), Hindle and Priest (1978), Williams, Cram and others (1978), Goyette and others (1977), Conners and others (1976), and Palmer and others (1975). Harley and others Phase I and Goyette and others suggested that the subgroup may be younger children, supporting Dr. Feingold's point that the younger the child, the more rapid and successful the improvement.³⁸

J. H. Williams (1979), Dumbrell and others (1978), and Harper and others (1978) agreed with Dr. Feingold that the K-P diet is nutritionally safe.³⁹ Eight studies reported behavioural improvement.⁴⁰ Four of these studies used the K-P diet, Breakey (1978), Brenner (1977), Noonan (1977), and Salzman (1976). O'Banion and others (1978) eliminated food additives. Harper and others (1978) eliminated food colours and flavours. J. H. Williams (1979) and Goyette and others (1977) eliminated food colours.

Three of the four animal studies summarized in Table 19.2, Augustine and Levitan (1978), Levitan (1978), and Shaywitz and others (1978), supported Dr. Feingold's rationale that food dyes may cause hyperkinetic behaviours.⁴¹

Table 19.2 Zoological Studies Related to the K-P Elimination Diet

Study	Subject	Purpose
1. Augustine, Levitan 1978	Frog	To examine sensitivity of vertebrate neuromuscular junction to FD & C Red #3 (erythrosin B, an anionic dye)
2. Carroll, Levitan 1978	Sea urchin gametes	To characterize the nature of the inhibition produced by anionic fluorescein dyes
3. Levitan 1978	Molluscs	To examine the effects which fluorescein dyes have on neuronal physiology
4. Shaywitz, Goldenring, Wool 1978	Rat pups	To study the effects of oral administration of 7 food dyes on activity levels and avoidance learning in normal developing rat pups and littermates treated with 6OHDA at 5 days of age

Table 19.2 (continued)

Results	Conclusions
1. Increase in activity	Erythrosin B has effects on both the pre- and post-synaptic members of the neuromuscular transmission FD & C Red #3 should be reviewed as an innocuous food additive
2. 6 derivatives of fluorescein rapidly inhibit fertilization of sea urchin gametes	This mechanism may cause subtle membrane changes that might block fertility in other species
3. Rapid increase in membrane potential and conductance of the neurons	The changes were a function of the dye and its concentration Food and drug additives may have predictable biological activities
4. A behavioural repertoire of hyperactivity and learning deficits similar to the clinical syndrome of attentional deficit disorder with hyperactivity (ADD) in children	These dyes may produce behavioural alterations in the developing rat pup

^bFor sources, see nn 19.42-19.45

The Carroll and Levitan study implied that genetics may be an etiological consideration for hyperkinesis and that food dyes may be a function of that genetic basis, as Dr. Feingold has suggested.⁴⁶

A WORD FROM THE CRITICS

The critics have made three major statements concerning K-P elimination diet studies; they express a concern shared by many critics, they suggest a possible therapeutic application of the K-P diet, and, they offer a recommendation that brings this research investigation full circle, so that its end is its beginning. Kinsbourne summed up the one concern that only time may yet determine. He postulated that the K-P diet may be judged to be a successful therapy for hyperkinetic children only when it sustains its apparent short-term success over the long-term.⁴⁷ The American Academy of Pediatrics has urged parents not to use the K-P diet on a long-term basis.⁴⁸ Esther Wender, and Bierman and Furukawa, pointed out that the long-term nutritional effects of the K-P diet are unknown.⁴⁹ Divoky, and Levine and Liden, added that the K-P diet may have long-term toxic effects.⁵⁰

In regard to a possible therapeutic application of the K-P diet, Kinsbourne, and Spring and Sandoval, suggested that the Feingold diet may be used in combination with other treatments.⁵¹

Levy and others, and others, recommended further

research into the efficacy of the K-P diet.⁵² Like Dr. Feingold, Williams and Cram specified that the mechanism by which food chemicals act on the CNS (central nervous system) requires examination.⁵³ William, Cram and others recommended longer time frames to test the efficacy of the K-P diet over a longer time period.⁵⁴ The critics' call for further research echoes Dr. Feingold's words spoken in 1973:

The recognition that food additives are linked to H-LD would make these chemicals valuable tools for studies on the neuropharmacologic aspects of behavior, not only as concerns H-LD but also in various other behavioral and emotional disturbances in man. Such studies could be extremely helpful in future planning of food supplies for a growing population that will become more and more dependent upon synthetic food products, most of which will be flavored and colored with artificial additives.⁵⁵

SUMMARY

Results from the twenty-five studies summarized on the K-P diet are varied. Some studies suggested a possible link between children's behaviours and the ingestion of artificial food colours and flavours. Some studies suggested that Dr. Feingold's K-P diet improves the behaviours of some hyperkinetic children. Some studies did not support Dr. Feingold's K-P diet-behaviour link. Some studies were inconclusive.

The four zoological studies that were summarized examined the mechanism of the effects of dyes on an organism. One of these studies reiterated Dr. Feingold's concern that the diet-behaviour link may have a genetic base.

The critics have recommended that the K-P elimination

diet be used with reasonable discretion and that rigorous research continue, to test the efficacy of the K-P diet, particularly for long-term effects.

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V

SUMMARY OF THE EVALUATION
OF THE LITERATURE

Chapter 20

SUMMARY OF THE EVALUATION OF THE LITERATURE

As the critics bring this investigation of the literature full circle with their recommendation for further study, so do the results of research that this thesis has examined. Research into K-P elimination diet therapy for H-LD is extensive, but seemingly inconclusive. The literature appears neither to prove nor to disprove Dr. Feingold's claim that the K-P elimination diet improves the behaviours of hyperkinetic children and others.

This thesis has examined (1) Dr. Feingold's view of hyperkinesis as H-LD, (2) his K-P elimination dietary management for H-LD, and (3) studies that test the efficacy of Dr. Feingold's K-P dietary management. Supporting and opposing views in the literature have been reported concurrently with each of the above three issues. Based on the evidence presented, an equally valid argument may be construed either for, or against, the K-P elimination diet for hyperkinetic children and others.

Until the controversy is resolved, perhaps a valid course of action for those involved in educating hyperkinetic children may be to know each child as an individual and to let that individuality be the measure of the treatment for that child.

VI

A GRASS-ROOTS OBSERVATIONAL REPORT
OF CHILDREN ON DR. FEINGOLD'S K-P
(KAISER-PERMANENTE) ELIMINATION
DIET FOR HYPERKINETIC CHILDREN
AND OTHERS

Chapter 21

INTRODUCTION

The report of remarkable improvement in academic and social behaviours of a 10 year old boy within a 3-month period on Dr. Feingold's K-P elimination diet prompted my interest in his particular case and led me to investigate possible behavioural effects of the K-P diet on nine other children in Regional Niagara during the past year (1979). The following information on the boy who prompted my interest in the K-P diet was gathered when he was 12.5 years old and had been on the diet for 2.7 years.

Before he began the K-P elimination diet in November, 1976, at age 10, the boy scored 15 out of 50 in the pre-school characteristics and 19 out of 50 in the grades 1-8 characteristics on the NYICD (New York Institute for Child Development) Learning Disabilities Checklist.¹ His final grade 1 achievement description for 1972-73 suggested hyperactive behaviours. It read as follows:

Grade 1	1972-73	Achievement Description
	Hyperactive	
	Inattentive	
	Poor co-ordination	
	Cannot sit still long	- Cannot complete work
	Short attention span	
	Mathematics	- Good understanding

The boy began the K-P diet near the end of term 1 during his grade 5 year. His penmanship, which would involve hand-eye and small muscle co-ordination, remained unsatisfactory (U) for term 2. However, his work habits and academic achievement were reported to be satisfactory (S), with improvement in Language Arts, Mathematics, and Social Studies. His term 2 report read as follows:

Grade 5	1976-77		Term 1	Term 2
Work Habits				
	Literature		U	S
	Penmanship		U	U
	Language		U	S
	Mathematics		U	S
	Social Studies		U	S
	Science		S	S
Achievement				
	Basic Mathematics		U	S
	Social Studies		U	S
	Science		S	S

Parental evaluation of the boy's improvement on the K-P diet was reported as follows:

April, 1977 - good success, elation;

March, 1978 - a dramatic change;

June, 1979 - many of the NYICD characteristics
have disappeared.

REFERENCES

Learning Disabilities Checklist, The New York
Institute of Child Development, 1976.

Chapter 22

METHOD

The nine subjects involved in the observational report were chosen on a voluntary basis. There were eight males and one female, with an age range from 3.5 to 11.5 years and mean age of 7.0 years. Each subject received a subject data kit to be completed and returned within a time agreed upon for each individual. The subject data kit included the following:

1. Personal data sheet
2. NYICD Learning Disabilities Checklist
3. Five 7-day diet diary sheets
4. Behaviour rating scale
5. Feingold K-P elimination diet
6. General instructions for K-P dietary management.¹

The NYICD Learning Disabilities Checklist is used in this observational report as an instrument to identify hyperkinetic behaviours because it is recognized by FAUS as a criterion for hyperkinetic behaviours. A child with 10 or more characteristics at the pre-school and/or grades 1 to 8 level is considered to be a child who may benefit from the K-P elimination diet. FAUS bases its rationale for using the NYICD checklist on NYICD's explanation that, "if you answer 'yes' to at least 10 (or 20%) of the questions, it may be that your child has a learning disability".²

The daily behavioural rating was recorded at the end of each day on the daily diet sheets for each subject according to the following scale:

- 4 A-OK, like other kids
- 3 Noticeable improvement
- 2 Holding -- just another day
- 1 Cranky, unhappy day
- 0 Total chaos

Each subject in this sample was his/her own control. All nine subjects followed the complete K-P elimination diet as closely as possible. When they participated in this investigation, six subjects were new to the K-P diet and three were already on the diet (Table 22.1). Of the six new subjects, only one, S_5 , recorded a base-line diet, for 5 weeks 4 days, before beginning the K-P diet. The remaining five new subjects began the K-P diet immediately, without establishing a base-line period. Follow-up data were obtained for S_2 , S_4 , and S_7 .

Table 22.1 Period of Observation

Subject	Dates Observed (inclusive)	Number of Years Previously on K-P Diet	Number of Days Observed
1	Oct. 1 - Oct. 21/79	0.4	21
2	Jan. 1 - Jan. 31/79	0.2	31
3	March 6 - April 9/79	0.0	35
4	March 6 - April 9/79	0.0	35

Table 22.1 (continued)

Subject	Dates Observed (inclusive)	Number of Years Previously on K-P Diet	Number of Days Observed
5	Feb. 15 - April 23/79	0.0	68
6	May 28 - June 9/79	0.0	13
7	April 30 - June 17/79	0.0	49
8	March 6 - March 12/79	0.0	<u>7</u>
	March 25 - March 31/79		<u>7</u> 21
	April 3 - April 9/79		<u>7</u>
9	May 11 - May 17/79	1.2	<u>7</u>
	July 7 - July 27/79		<u>21</u> 28

REFERENCES

¹Personal Data Sheet, see Appendix, p. 195;
 Seven-Day Daily Diet Sheet, see Appendix, p. 196.

²Learning Disabilities Checklist, The New York
 Institute for Child Development, 1976.

Chapter 23

RESPONSE

The response of the nine subjects in the observational report falls into two categories, a statistical response and an anecdotal response.

STATISTICAL RESPONSE

Seven of the nine subjects observed scored over ten on the NYICD Learning Disabilities Checklist. One subject scored ten, and one subject scored nine (Table 23.1).

Table 23.1 Scores on NYICD Learning Disabilities Checklist

Subject		Characteristics		
Number	Age	Pre-School (50 items)	Grades 1-8 (50 items)	Total
1	11.5	1	11	12
2	6.11	15	17	32
3	5.3	10	0	10
4	7.10	13	10	23
5	4.4	8	1	9
6	3.5	12	0	12
7	7.9	27	28	55
8	8.5	0	13	13
9	7.11	2	10	12

The daily behavioural ratings yielded two types of data, (1) behavioural trends and (2) a suggested infraction-time-behavioural link.¹

Behavioural Trends

The three subjects already on the K-P elimination diet at the beginning of the observational period, S_1 , S_2 , and S_9 , had different behavioural rating patterns. S_1 , already on the K-P diet for four months, began the 21-day observational period with a behavioural rating of 0. Throughout the entire period, the rating fluctuated between 0 and 4 and stabilized at 4 for the final three days, four ratings higher than at the beginning.

S_2 , already on the diet for two months, began the 31-day observational period with a behavioural rating of 0. The rating rose one level at a time for the first nineteen days, punctuated by a drop to 1 between each rise. Between days 22 and 31 the behavioural rating ranged between 0 and 2, ending at 2 for the last two days of the observational period, two ratings higher than at the beginning.

S_9 , already on the K-P diet for one year and two months, began the 28-day observational period with a behavioural rating of 3 for the first three days. Between days 5 and 12 the pattern fluctuated between 1 and 4. For the remainder of the observational period the rating ranged between 3 and 4 and levelled off at 4 for the final three days, one rating higher than at the beginning.

Subjects three to eight were new to the K-P elimination diet at the beginning of the observational period. The behavioural ratings were not recorded for S_3 for days 1, 2, 26, and 27, nor for S_4 for days 2, 26, and 27.

S_3 began the 35-day observational period with a behavioural rating of 2 and reached a rating of 4 by day 15. Between days 28 and 35 the rating ranged between 3 and 4, ending at 3 on day 35, one rating higher than at the beginning of the observational period.

S_4 began the 35-day observational period with a behavioural rating of 0. On day 4 the rating rose to 2 and by day 13 it reached 4. Between days 13 and 35 the rating was generally 4, with two drops to 1. The rating levelled off at 4 for the final six days, four ratings higher than at the beginning of the observational period.

On both the base-line diet and the K-P diet, the behavioural rating for S_5 was generally 3, with fluctuations that ranged from 0 to 4 during the 68-day observational period. The rating of 4 on day 68 was one rating higher than the behavioural rating of 3 on day 1.

S_6 began the 13-day observational period with a behavioural rating of 1 for days 1 and 2, and the rating rose steadily to 4 by day 4. For the remainder of the observational period, the rating ranged between 2 and 4 and dropped to 2 for the final 2 days, one rating higher than at the beginning.

S₇ began the 49-day observational period with a behavioural rating of 2. Between days 3 and 8 the rating ranged between 0 and 2 and on day 10 it rose to 4. For the remainder of the observational period, the rating ranged between 2 and 4, levelling six times at 4 for 2- to 8-day periods. The rating for the final two days was 4, two ratings higher than at the beginning of the observational period.

For nineteen of the twenty-one days observed, S₈ had a behavioural rating of 4 that dropped to 1 twice, on days 11 and 17. The rating of 4 for the final four days of the observational period was the same as the rating for the first nine days.

Infraction

The forty-eight infractions noted in the data for the nine subjects fall into three time-related categories, (1) an immediate adverse behavioural effect, i.e., a drop in the rating to 0, total chaos, or to 1, cranky, unhappy day, on the day of the suspected infraction, (2) a delayed adverse behavioural effect, i.e., a drop in the rating to 0 or 1 by the end of the day that followed the suspected infraction, and (3) a carry-over of an adverse behavioural effect, i.e., a rating of 0 or 1 that continued beyond the first day of the drop to the 0 or 1 rating. Infractions appeared to result in more immediate drops in behavioural rating to 1 (28) than to 0 (5), in more delayed drops in

rating to 0 (6) than to 1 (4), and in almost the same number of 0 and 1 ratings in carry-over incidence, (3) and (2) respectively. (See Table 23.2.)

Table 23.2 Incidence of Infraction in Relation to Behavioural Ratings of 0 and 1 and Possible Causes

Possible Causes	Number of Infractions							
	Immediate		Delayed		Carry-Over		Total	
	Rating	0 1	0 1		0 1			
Away from home		1		1			2	
Christmas holidays					1 2		3	
Illness		1					1	
Mealtime								
-Breakfast	1	5	2				8	
Lunch	1	8	1				10	
Supper	1	6	3 3		1		14	
Medication	1	5					6	
Off K-P diet for the day		2					2	
Specific challenge - Breakfast	1				1		2	
Total		5 28	6 4		3 2		48	

Mealtimes appeared to account for thirty-four of the forty-eight infractions that resulted in a drop of behavioural rating to 0 or 1, for the nine subjects, during the observational period, in all three time-related categories. One day off the K-P diet appeared to result in

an immediate drop in the behavioural rating of 1 for S_2 on day 14 and for S_4 on day 25.

On day 24, S_2 began medication that was coloured and flavoured, for an illness, and the behavioural rating immediately dropped to 0. The rating rose one level, to 1, and stayed there for the five days that S_2 remained on the medication.²

Specific challenge may have accounted for the intentional infraction that resulted in an immediate drop to a 0 rating for S_1 , who had been on the K-P diet for over a year at the beginning of the observational period. S_1 was given raisins on day 6, at breakfast-time, to test for salicylate tolerance. The immediate drop to 0 rating suggests that S_1 experienced intolerance to the raisins when they were re-introduced into the diet. The rating of 0 on the following day, day 7, suggests a wash-out effect; i.e., the behavioural rating dropped to 0 while the effect of the salicylate challenge may have been wearing off.

S_2 may have experienced a carry-over effect from the Christmas holidays that resulted in the behavioural rating of 0 the first day back on the K-P diet, and the rating of 1 for the next two days, during a possible wash-out period. S_7 's day 7 rating of 0, two days after an immediate drop in rating to 1 that possibly resulted from a suppertime infraction on day 5, may be another example of the wash-out effect.

ANECDOTAL RESPONSE

The anecdotal response includes parent and school reported behaviours and comments, for Ss₁₋₇ and S₉. There were no behavioural comments recorded for S₈.

Parent-Reported Behaviours

The three subjects already on the K-P elimination diet at the beginning of the observational period, S₁, S₂, and S₉, had parental comments. S₁'s mother reported constant, or quick, talking and interrupting others on low behaviour rating days. She reported that he refused a hot chocolate drink on one occasion, at a friend's, and apple pie on another occasion, at home, because 'he doesn't like the feeling it would give to him'. S₂'s mother reported that on an infraction day of aspirin and ginger ale, incessant chattering contributed to a behavioural rating of 1. S₉'s mother noted enuresis on two days as a possible monthly occurrence.

Parental reporting of the behaviours of subjects who were new to the K-P diet at the time of the investigation included the following comments:

- S₃ - very talkative
- S₄ - follow-up comment-new friends
- S₅ - see big difference on Feingold diet
- S₆ - sugar seems to cause the biggest reaction
- S₇ - follow-up comments--summer was pure chaos
while off diet, so different now
- tremendous for whole family.

School-reported Behaviours

There were school-reported behavioural comments for two subjects who were already on the K-P diet at the time of the investigation, S_1 and S_2 , and for two subjects new to the diet, S_4 and S_7 .

S_1 - test marks in French and Spelling were improved
 passing grades
 no more remedial help needed
 enjoys school

S_2 - Reading vocabulary]	improved
Reading comprehension		
Oral Mathematics		
Writing]	poor
small muscle co-ordination		
follow-up		

- June, 1979

- Silver Medal - for being most improved pupil
 in the class for the year

- October 31, 1979

- listening skills]	improved
attitude toward peers		
Printing		
hand control		
quieter - in tone of voice		
on-task		

S₄ - follow-up

- slight improvement noted

- parent - 'not necessarily attributable
to K-P diet'

S₇ - Day 1 - running

teacher had to restrain S

talkative

Days 2-5 - took time - neat printing

follow-up

- finishes assignments

advancing ahead of class on own.

REFERENCES

¹See below, Daily Behavioural Rating Graphs 23.1-23.9, Appendix, pp. 197-201.

²See above, pp. 66, 96.

Chapter 24

DISCUSSION

The nine subjects observed were a heterogeneous group. The research design was mainly anecdotal and has little or no statistical value in terms of either reliability or validity.

The behavioural rating for the final day for all nine subjects did not drop below their rating for day 1, suggesting that the K-P elimination diet did not cause adverse behavioural effects during the observational period. S_9 , who had been on the K-P diet for over a year, had a final rating of 4 that was the same as the rating for day 1, suggesting that the A-OK, like other kids behaviours previously established, were maintained by the K-P diet. The rise of four ratings for S_1 , who had been on the diet for four months, suggests significant improvement during the observational period. The rise of one rating for S_2 , already on the K-P diet for two months, suggests slight or no improvement during the observational period.

Of the subjects new to the K-P elimination diet at the beginning of the observational period, S_8 's rating pattern suggests that the K-P diet maintained previously established A-OK, like other kids behaviours during the observational period. The rapid rise of rating for S_6 from

1 to 4 within three days suggests rapid initial improvement on the K-P diet. However, the final rating of 2, one rating higher than at the beginning, and, the low behavioural improvement designated by ratings 1 - cranky, unhappy day, and 2 - holding-just another day, suggests that an apparent early dramatic improvement was followed by minimal or no improvement on the K-P diet during the observational period. The rise of one behavioural rating for S_3 and S_5 suggests little or no improvement.

The rise of two ratings for S_7 suggests improvement on the K-P diet during the observational period not only statistically, but also by the behaviours designated by the rating of 2 for day 1 and the rating of 4, A-OK, like other kids, for the final day, day 49. S_4 's increase in rating of four strongly suggests improvement on the K-P diet during the observational period.

The drop in the behavioural rating for S_3 between days 5 and 7, and the fluctuating pattern of 0 to 2 ratings for S_7 between days 2 and 8, may indicate a period of adjustment to the K-P elimination diet during the first week, as pointed out by Breakey.¹ The fluctuating behavioural ratings for S_6 between days 9 and 13 may indicate that an adjustment period may occur later than within the first week on the K-P diet, for some children.

There may be a relationship between infraction, that is, the ingestion of food not on the K-P elimination

diet, and the period of time in which adverse behaviours occur that result in a drop in behavioural rating to 0, total chaos, or 1, cranky, unhappy day. Delayed adverse behavioural effects caused by infractions appear to be more severe than immediate effects.

S₄'s mother suggested that the improvement noted at school may not be attributable to the K-P diet. Perhaps behaviour modification is a factor. S₇'s noticeable school improvement may also be attributable to behaviour modification. Being allowed to advance ahead of his class on his own may be providing the child with positive reinforcement that motivates both his academic ability and his self-concept, and may result in improved school behaviours.

Enuresis was reported for only one subject, S₉. Dr. Feingold included enuresis as one of the conditions besides hyperkinesis that may be improved by the K-P diet.²

Talkativeness is reported as an adverse behaviour at home for three subjects, S₁, S₂, and S₃, and at school for one, S₇. Although Dr. Feingold does not include talkativeness in his Excitable-impulsive characteristic of H-LD, there may be a possible relationship between them that may warrant further research.

REFERENCES

¹See above, p. 122.

²See above, p. 70.

Chapter 25

CONCLUSION

This grass-roots observational report does not conclusively answer the question of support for Dr. Feingold's claim that the K-P elimination diet improves the behaviours of some hyperkinetic children, and other children as well. From the anecdotal point of view the report would appear to support Dr. Feingold's behavioural claim. From the statistical point of view, the observational report is neither valid nor reliable. Voluntary reporting is not a measurable, rigorous design. The small sample in this investigation, nine children, has little impact on existing evidence.

Rigorous studies could be considered on a regional basis to investigate the following:

1. the effects of the K-P elimination diet on subjects new to the K-P diet, at home and at school;
2. the effects of challenge on academic achievement of children already on the K-P diet;
3. the implementation of academic programmes for children who appear to have improved behaviours on the K-P diet.

There appears to evidence that suggests that the K-P elimination diet helps some children. However, the diet may simply be nutritionally better for certain children than their 'normal' diet--hence an improvement.

(Data available on request.)

VII

THESIS SUMMARY

Chapter 26

THESIS SUMMARY

PROBLEM

Do evaluation of the literature and a regional observational report support Dr. Feingold's claim that the K-P (Kaiser-Permanente) elimination diet improves the behaviours of hyperkinetic children and others?

Dr. Feingold suggests that some hyperkinetic children, and other children as well, are genetically predisposed to intolerance of food additives, particularly food colours and flavours. He claims that the K-P diet, that eliminates salicylates and artificial food colours and flavours, improves the hyperkinetic child's behaviour, muscle co-ordination, and scholastic performance. Public acceptance of the K-P elimination diet has outstripped acceptance in the medical and scientific communities. If there is a diet-behaviour link, there could possibly be educational ramifications. Improved behaviours may improve a child's progress through our educational structure in Ontario, academically, psychologically, and sociologically.

RESEARCH METHODOLOGY

This thesis was an investigation of two different

approaches to the question of Dr. Feingold's K-P elimination diet for hyperkinetic children and others. It reported and analyzed, first, the literature dealing with Dr. Feingold's philosophy of H-LD (hyperkinesis-learning disability) and his K-P elimination diet, and second, it reported a grass-roots observational investigation of nine cases, that was conducted in Regional Niagara over a nine-month period.

FINDINGS

The literature generally supports Dr. Feingold's concept of H-LD. Dr. Feingold, in turn, has made two contributions to the literature on childhood hyperkinesis:

1. he has added a new label, H-LD, and
2. he has introduced a new focus that is compatible with education -- he focuses on the individual child.

The literature also generally accepts Dr. Feingold's rationale that the K-P diet is safe and nutritious. However it criticizes the absence of valid, reliable data to substantiate his claims that the diet improves the psychological, sociological, and academic behaviours of some hyperkinetic children, and other children as well.

Studies conducted to test the efficacy of the K-P diet yield inconsistent, contradictory evidence, so that results are inconclusive. On the whole, these studies appear neither to prove nor to disprove Dr. Feingold's behavioural claims for the diet. The Regional Niagara

grass-roots report of nine cases offers some support for the K-P diet. However, owing to its anecdotal design, it is neither valid nor reliable, and is, therefore, inconclusive.

The K-P diet has produced benefits in the consumer sector. FAUS (Feingold Association of the United States) has been voluntarily organized by lay-people to monitor, report, and analyze marketing of food, scientific findings in nutrition, government action in relation to the food industry, results of K-P dietary management, and suggestions for further action in all of these areas. Consumers are becoming increasingly aware and involved as they question the ingredients of products in the market-place in our ecologically oriented society.

CONCLUSIONS AND RECOMMENDATIONS

The speculative analysis of Dr. Feingold's research data in this thesis supports the literature's criticisms that (1) the data Dr. Feingold reported are incomplete, inconsistent, and imprecise, and (2) that Dr. Feingold's data do not statistically validate his behavioural claims for the K-P elimination diet for hyperkinetic children and others. Dr. Feingold's rationale appears to be based mainly on anecdotal reports of clinical observations. The regional grass-roots report of nine cases has limited value as evidence. However, it does indicate parental interest and voluntary involvement in improving their child's behaviours.

Findings of the studies in the literature of the K-P elimination diet and findings of the Regional Niagara grass-roots observational report suggest that there may be a subset of children, including hyperkinetic children and others, that responds with improved behaviours on the K-P diet. The responding subset needs to be identified and defined. For hyperkinetic children and others who respond favourably to the K-P diet, academic programmes may be designed to compensate for deficit or developmental lag which may have occurred. Studies may be conducted to test the effects of challenge to the K-P diet on the academic behaviours of children who respond favourably to the diet. As suggested by J. H. Williams (February, 1979) and Kinsbourne (November 8, 1979), the weight and/or age of the child may be correlated to the K-P diet challenge dosage. Studies may be conducted to investigate this possibility.

A behavioural rating scale that indicates the number of times specific behaviours occur, rather than whether they occur, as a checklist indicates, may help to establish norms from which a reliable scale may be developed for use with hyperkinetic children. A standardized behavioural scale may help to define hyperkinesis and may also improve the validity of parent and teacher reporting.

As Dr. Marcel Kinsbourne, of Sick Children's Hospital, Toronto, Canada, commented in St. Catharines, Ontario, during his Year of the Child lecture on "Hyperactivity in Young Children", "If it helps, I'm for it. If it harms,

I'm against it" (November 8, 1979). Besides a possible physical improvement for the child, there may be a psychological improvement in family dynamics as everyone in the family works together to make the K-P diet work. The K-P elimination diet may be beneficial when used in combination with other therapies, such as family counselling, behaviour modification, remedial or special education programmes.

Neither the literature nor the grass-roots report yield sufficient evidence to answer conclusively the question of Dr. Feingold's claim that the K-P elimination diet improves the behaviours of some hyperkinetic children, and other children as well.

The issue of Dr. Feingold's K-P elimination diet for children with H-LD, and others, is far from resolved. Common sense suggests that if the diet works, use it; if it doesn't, don't. The role of education in this issue is (1) to keep informed, (2) to keep an open mind, and (3) to help each child to achieve academic success and self-fulfillment.

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APPENDICES

SUBJECT DATA INFORMATION SHEET
FOR THE OBSERVATIONAL REPORT

1. Personal data sheet
 - please fill this out
2. Checklist of characteristics
 - please check beside characteristics that apply
3. Five 7-day diet diary sheets
 - please keep this record for 3 - 4 consecutive weeks
 - fill in Symptoms spaces only if you suspect an infraction, or if you think that a symptom, or characteristic, is significant at the time
 - feel free to jot comments on the back of these sheets, particularly regarding infractions, and write the date each time, please
4. Behaviour rating scale
 - please assign the number from 0 - 4 that applies to each day at the bottom of each day's diet entries on the 7-day diary sheet
 - if this rating scale is not applicable, please contact me and we'll work one out that works for you
5. Feingold K-P elimination diet material
 - Feingold diet - Group I
Group II
 - salicylate-free safe food list - Phase I
 - updated material
 - general instructions

Thank you very much for contributing to the data from the Niagara Region for my M. Ed. thesis, Brock University, St. Catharines, Ontario, regarding Dr. Feingold's K-P elimination diet for hyperkinetic children and others.

Mrs. Joanne S. Campbell.

Mrs. Joanne S. Campbell.

PERSONAL DATA SHEET

Name:

Address:

Telephone number:

Birth date:
 year month day

Present school grade or class:

Nature of diet: i) entire K-P diet

 ii) modified K-P diet

- if you checked (ii) modified K-P diet, please list the parts of the K-P diet you use, on the back of this sheet

Improvements since on diet:

- please list below under the appropriate heading
- if there is not enough space, list on the back of this sheet under each heading

Behaviour

Academic

Comments or questions:

Name _____

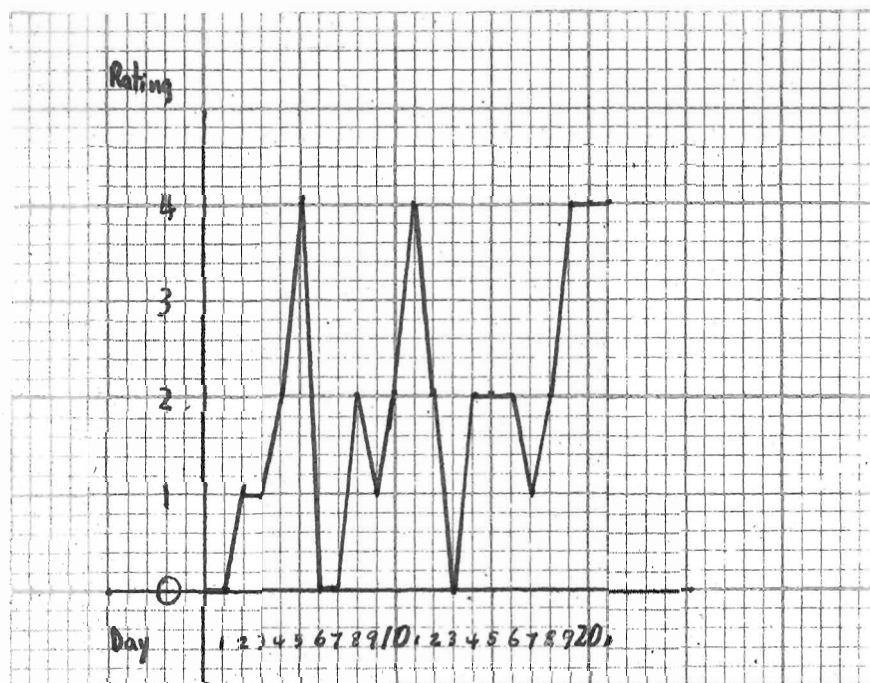
7 Day Diet Diary

Date _____

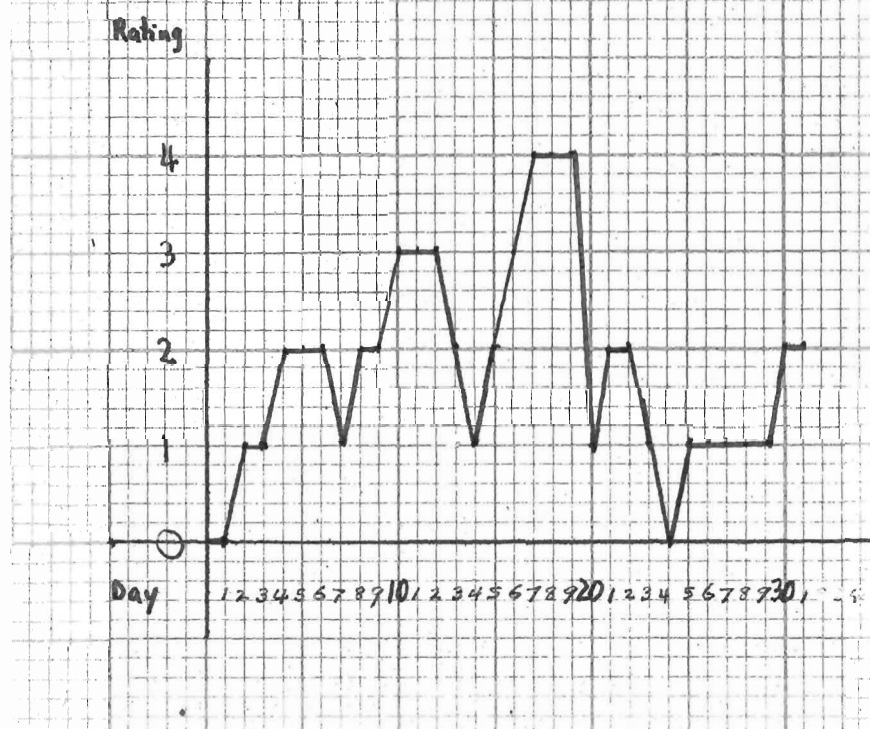
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BREAKFAST						
SYMPTOMS						
LUNCH						
SYMPTOMS						
DINNER						
SYMPTOMS						

DAILY BEHAVIOURAL RATING GRAPHS
23.1 - 23.9

23.1

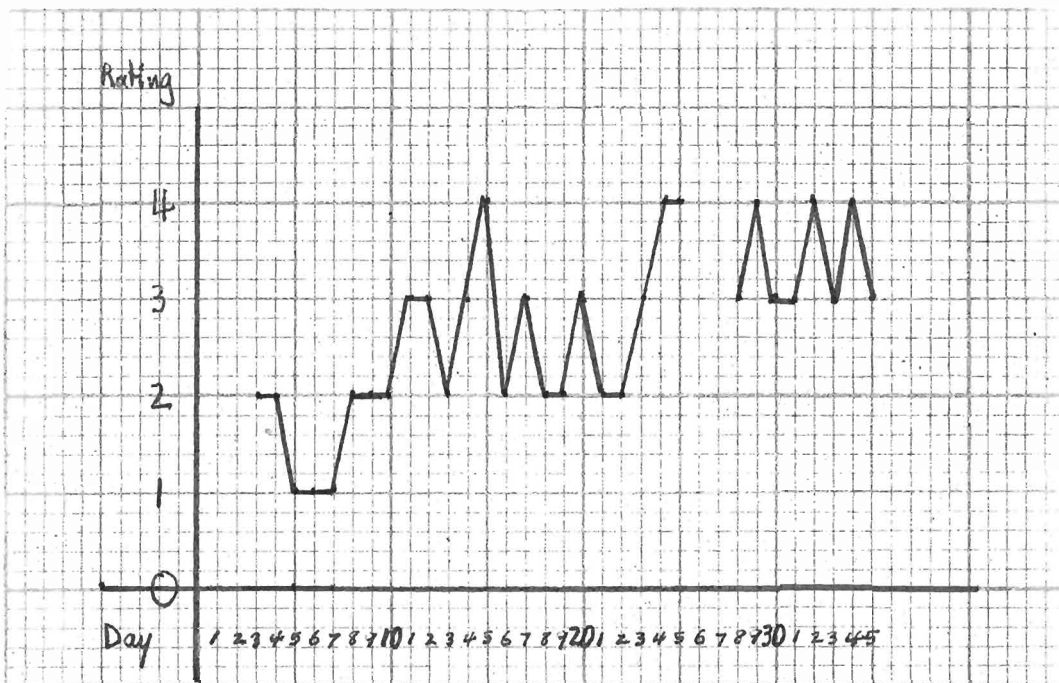


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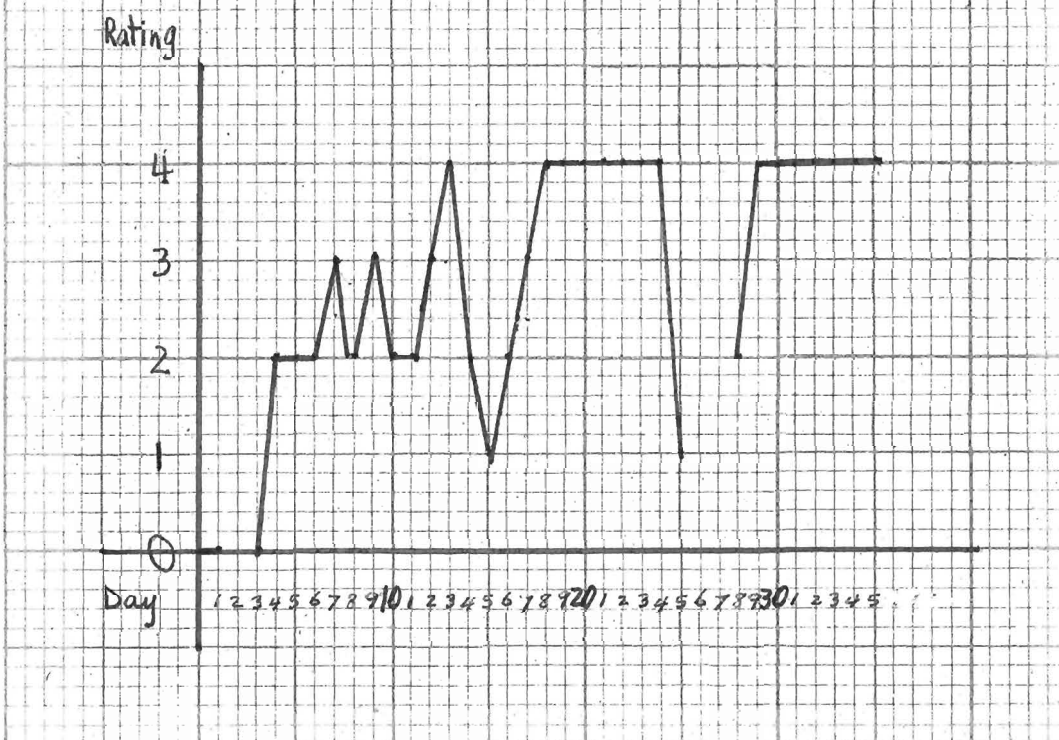


DAILY BEHAVIOURAL RATING GRAPHS
23.1 - 23.9 (continued)

23.3

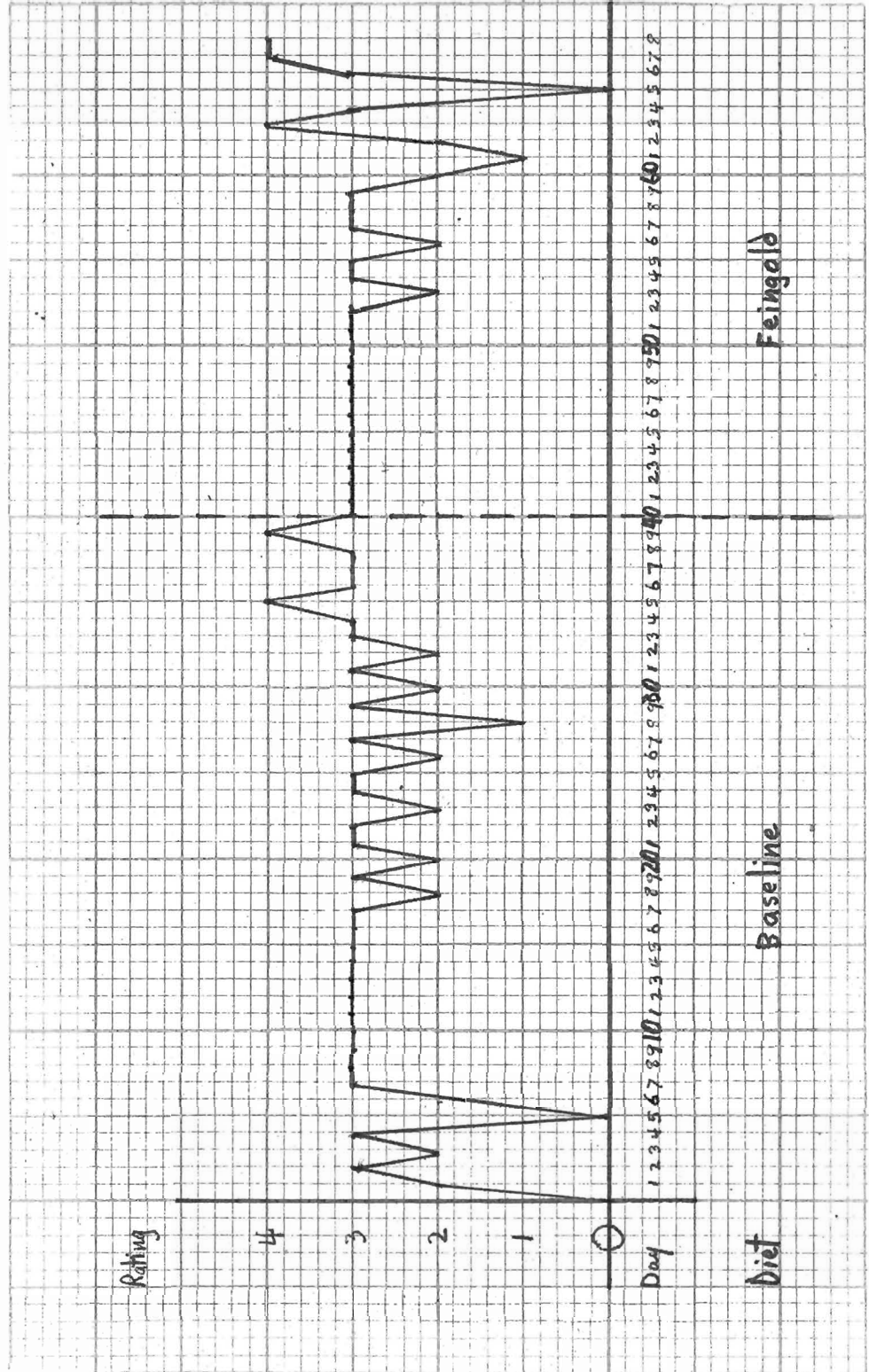


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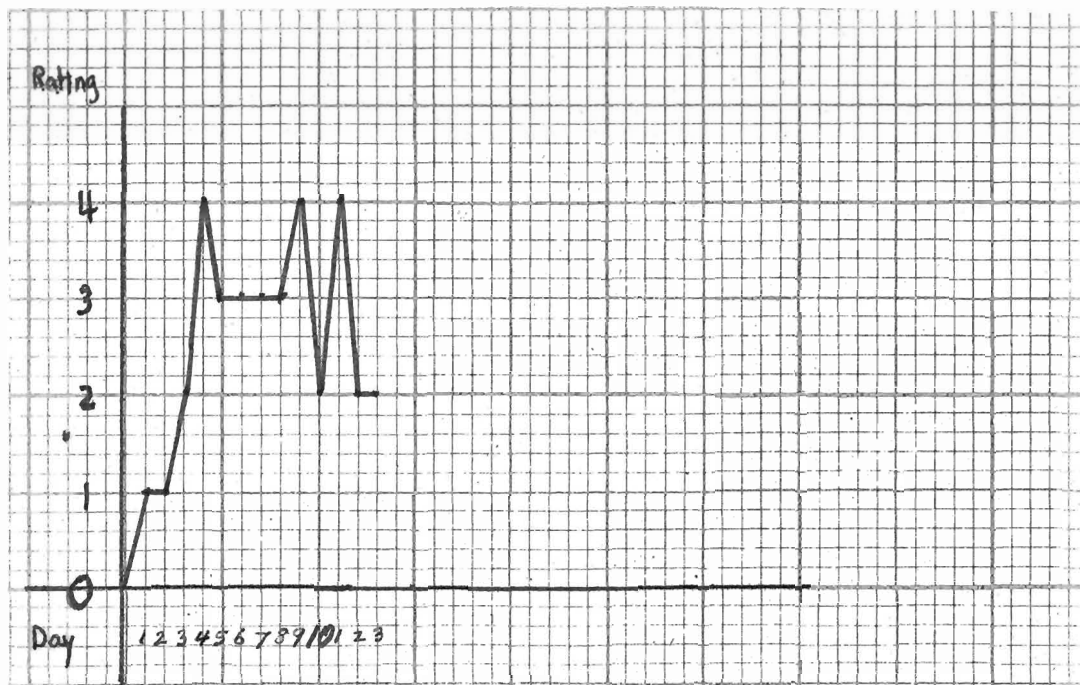
DAILY BEHAVIOURAL RATING GRAPHS
23.1 - 23.9 (continued)

23.5

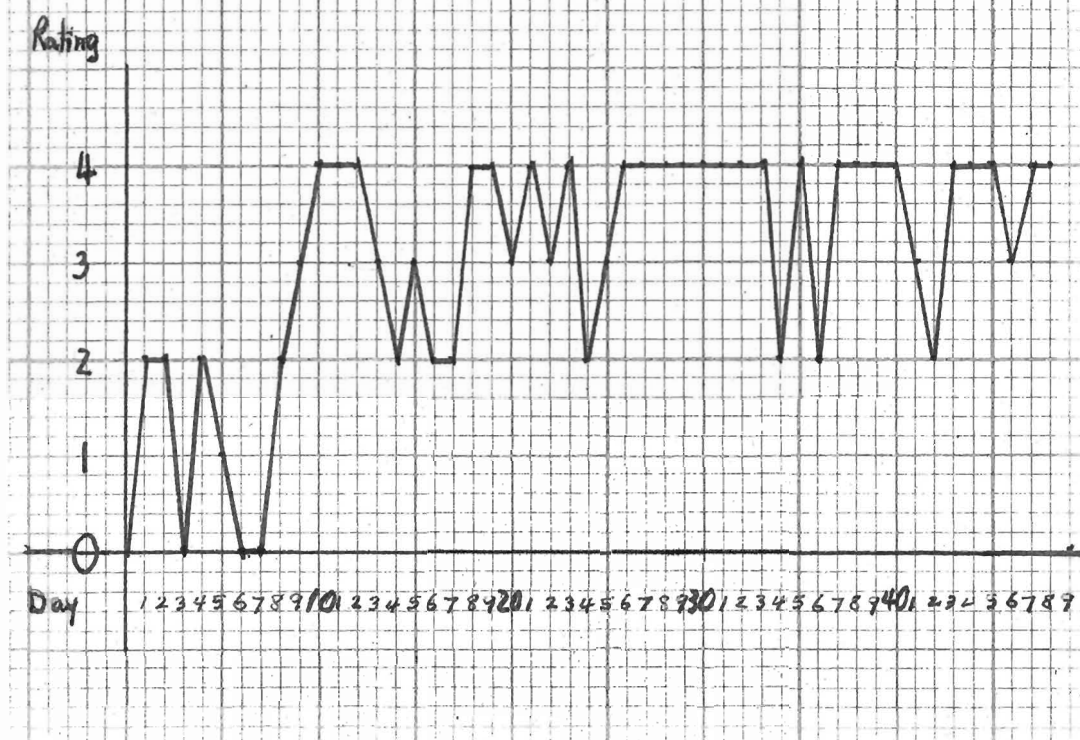


DAILY BEHAVIOURAL RATING GRAPHS
23.1 - 23.9 (continued)

23.6

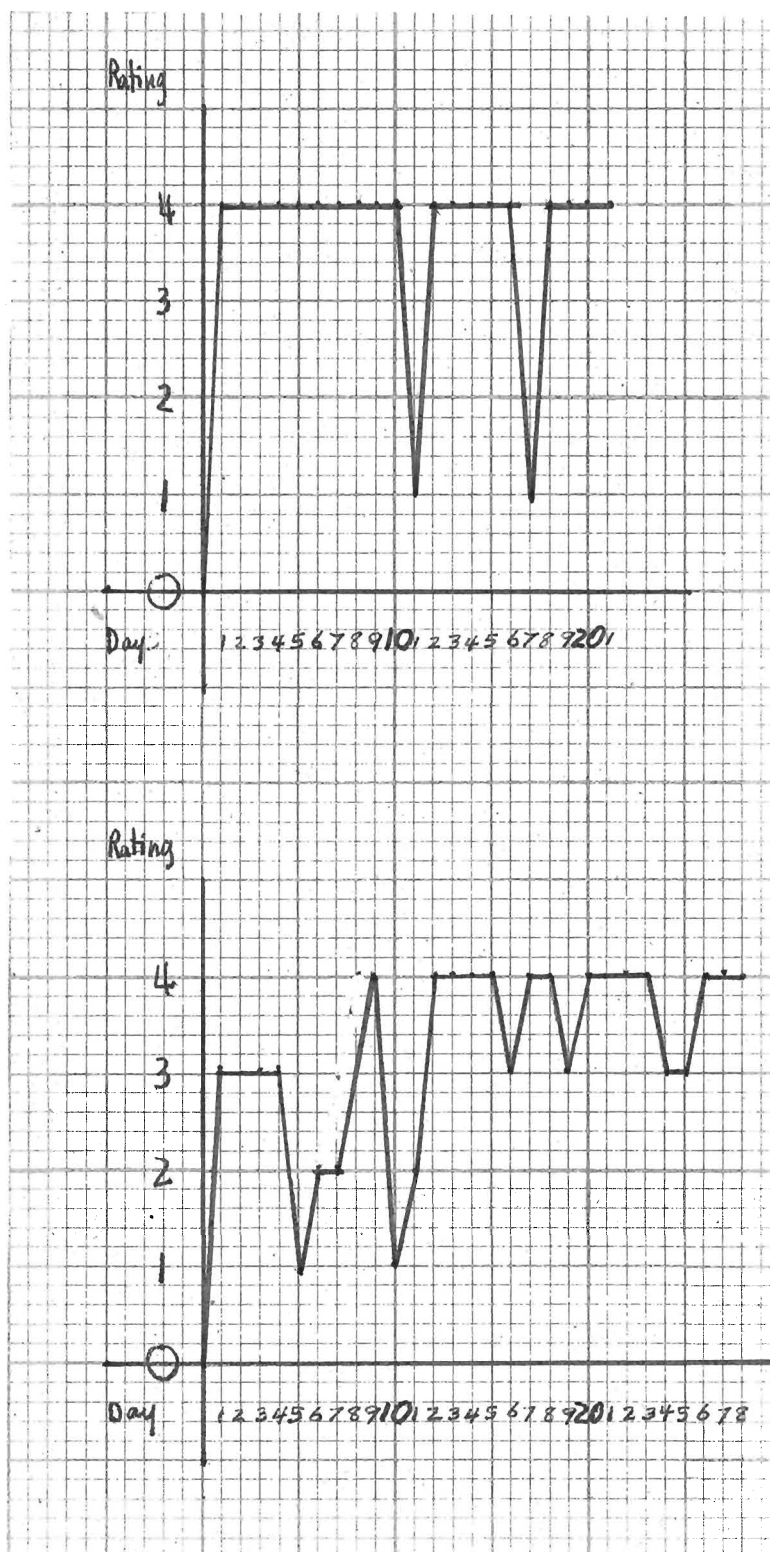


23.7



DAILY BEHAVIOURAL RATING GRAPHS
23.1 - 23.9 (continued)

23.8



23.9

